

EXHIBIT J

Brian Flynn, M.D.

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 _____
5 IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS
6 LIABILITY LITIGATION

7 _____
8 MASTER FILE NO. 2:12-MD-02327
9 MDL NO. 2327

10 _____
11 GENERAL CAUSATION RE: TVT-O

12 _____
13
14
15 PURSUANT TO NOTICE, the deposition of BRIAN
16 FLYNN, M.D. was taken on behalf of the Plaintiff at
17 Denver Marriott West, 1717 Denver West Boulevard,
18 Golden, Colorado, on April 14, 2016, at 8:42 a.m.,
19 before Melanie L. Giamarco, Registered Merit Reporter,
20 Certified Realtime Reporter, and Notary Public within
21 Colorado.

22
23
24 GOLKOW TECHNOLOGIES
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Brian Flynn, M.D.

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<p>1 A P P E A R A N C E S</p> <p>2 For the Plaintiffs:</p> <p>3 JOSEPH ZONIES, ESQ.</p> <p>4 GREG BENTLEY, ESQ.</p> <p>5 SHEA SHAVER, ESQ.</p> <p>6 ZONIES LAW, LLC</p> <p>7 1900 Wazee Street</p> <p>8 Suite 203</p> <p>9 Denver, Colorado 80202</p> <p>10 For the Defendants Johnson & Johnson and</p> <p>11 Ethicon:</p> <p>12 BARRY J. KOOPMANN, ESQ.</p> <p>13 DAVID J. DUKE, ESQ.</p> <p>14 BOWMAN AND BROOKE, LLP</p> <p>15 150 South Fifth Street</p> <p>16 Suite 3000</p> <p>17 Minneapolis, Minnesota 55402</p>			<p>1 EXHIBITS</p> <p>2 NUMBER DESCRIPTION PAGE</p> <p>3 Exhibit 14 Study published in International Urogynecology Journal by Chahin Achdari, et al., entitled: Anatomical study of the obturator foramen and dorsal nerve of the clitoris and their relationship to minimally invasive slings 60</p> <p>4</p> <p>5</p> <p>6 Exhibit 15 Study published in BJU International, by Jean-Pierre Spinosa, et al., entitled: Transobturator surgery for female stress incontinence: a comparative anatomical study of outside-in vs inside-out techniques 61</p> <p>7</p> <p>8</p> <p>9</p> <p>10 Exhibit 16 Article published in Urology Times entitled: Slings for stress incontinence: Are all created equal? 65</p> <p>11</p> <p>12 Exhibit 17 The Cochran Collaboration review entitled: Mid-urethral sling operations for stress urinary incontinence in women 95</p> <p>13</p> <p>14</p> <p>15 Exhibit 18 Article published in Urogynecology by Dr. Funk entitled: Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors 99</p> <p>16</p> <p>17</p> <p>18 Exhibit 19 Article published in International Urogynecology Journal by Dr. Tommaselli, et al., entitled: Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis 101</p> <p>19</p> <p>20</p> <p>21 Exhibit 20 Article published in International Urogynecology Journal by Dr. Unger, et al., entitled: Indications and risk factors for midurethral sling revision 103</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>		
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<p>1 I N D E X</p> <p>2 EXAMINATION OF BRIAN FLYNN, M.D. PAGE</p> <p>3 March 24, 2016</p> <p>4 By Mr. Zonies 5</p> <p>5 By Mr. Koopmann 86</p> <p>6 EXHIBITS</p> <p>7 NUMBER DESCRIPTION PAGE</p> <p>8 Exhibit 1 Amended Notice to Take Deposition of Brian Flynn, M.D. 5</p> <p>9</p> <p>10 Exhibit 2 Compilation of letters and e-mails between Dr. Flynn and Johnson & Johnson, 16 pages 7</p> <p>11</p> <p>12 Exhibit 3 Master Consulting Agreement between Dr. Flynn and Ethicon, Inc. 8</p> <p>13</p> <p>14 Exhibit 4 Testimony list of Dr. Flynn 9</p> <p>15</p> <p>16 Exhibit 5 CV of Dr. Flynn 9</p> <p>17</p> <p>18 Exhibit 6 Compilation of letters between Dr. Flynn and Butler Snow 9</p> <p>19</p> <p>20 Exhibit 7 USB drive 12</p> <p>21 Exhibit 8 USB drive 12</p> <p>22 Exhibit 9 CD titled: Ethicon Gynecare Pelvic Mesh Litigation 13</p> <p>23</p> <p>24 Exhibit 10 Invoice of Dr. Flynn regarding preparation of TVT-O report 14</p> <p>25 Exhibit 11 TVT-O studies 18</p> <p>26 Exhibit 12 Expert Overview of TVT-Obturator 20</p> <p>27 Exhibit 13 Study published in Obstetrics & Gynecology by Christopher M. Zahn, et al., entitled: Anatomic Comparison of Two Transobturator Tape Procedures 58</p>			<p>1 P R O C E E D I N G S</p> <p>2 (Exhibit Number 1 was marked for</p> <p>3 identification.)</p> <p>4 BRIAN FLYNN, M.D.,</p> <p>5 after having been duly sworn, was examined and</p> <p>6 testified as follows:</p> <p>7 EXAMINATION</p> <p>8 BY MR. ZONIES:</p> <p>9 Q. Doctor, good morning.</p> <p>10 A. Good morning.</p> <p>11 Q. My name is Joe Zonies, and we've met</p> <p>12 before. I'm taking this deposition on behalf of the</p> <p>13 plaintiffs in this litigation. Do you understand</p> <p>14 that?</p> <p>15 A. I do.</p> <p>16 Q. And you understand this morning that we're</p> <p>17 going to talk about the TVT-Obturator device, correct?</p> <p>18 A. Correct.</p> <p>19 Q. I'm going to hand you what's been marked as</p> <p>20 Exhibit 1, the notice of deposition as amended. Have</p> <p>21 you seen this document before?</p> <p>22 A. I have.</p> <p>23 Q. And it requests that you bring certain</p> <p>24 things with you as well in Exhibit A. Did you bring</p> <p>25 anything with you today?</p>		

<p style="text-align: right;">Page 6</p> <p>1 A. I did.</p> <p>2 Q. And what is that?</p> <p>3 A. I have it in the center of the table.</p> <p>4 There are some e-mails between myself and Ethicon, my</p> <p>5 CV, my fee schedule, the notice of deposition. And</p> <p>6 then some of the items were submitted at the last</p> <p>7 deposition, like a contract, for instance, I had with</p> <p>8 Ethicon, so I responded to the notice.</p> <p>9 And I've brought also some USB drives. And</p> <p>10 the USB drives are articles that may or may not be</p> <p>11 included in these binders. So in addition to the</p> <p>12 USBs, I brought a binder here that has my expert</p> <p>13 report; it has all the articles that I've referenced</p> <p>14 in my expert report, my reliance list. I also have a</p> <p>15 CD here of articles on TVT-O, and then I have an</p> <p>16 invoice on TVT-O.</p> <p>17 Q. Okay. So let's go through those and mark</p> <p>18 them.</p> <p>19 MR. ZONIES: Can we go off the record a</p> <p>20 second?</p> <p>21 (A discussion was held off the record.)</p> <p>22 Q. (By Mr. Zonies) Doctor, I'm going to mark</p> <p>23 as Exhibit 2 one of the documents you brought with</p> <p>24 you.</p> <p>25 //</p>	<p style="text-align: right;">Page 8</p> <p>1 Johnson & Johnson sent out to all their preceptors,</p> <p>2 but that's not the actual contract.</p> <p>3 Q. And as of November 12th, 2013, did you have</p> <p>4 a consulting relationship with Johnson & Johnson?</p> <p>5 A. I have not.</p> <p>6 Q. And so did you receive this e-mail in error</p> <p>7 from Johnson & Johnson?</p> <p>8 A. Correct.</p> <p>9 Q. That's what I thought.</p> <p>10 A. I may have been listed as a preceptor, but</p> <p>11 I was not active, and I didn't have any binding</p> <p>12 contract.</p> <p>13 Q. Okay. You've also produced what I'll mark</p> <p>14 as Exhibit 3. And it has previously been marked as an</p> <p>15 Exhibit 5 in a deposition on January 7th, 2015,</p> <p>16 something entitled the "Master Consulting Agreement."</p> <p>17 (Exhibit 3 was marked for identification.)</p> <p>18 Q. Is this your contract that you had with</p> <p>19 Ethicon?</p> <p>20 A. This is dated March 5th, 2011. And this</p> <p>21 was a consulting agreement that I engaged with</p> <p>22 Johnson & Johnson/Ethicon.</p> <p>23 Q. And to your knowledge, is that the last</p> <p>24 consulting agreement you had with Ethicon?</p> <p>25 A. Correct.</p>
<p style="text-align: right;">Page 7</p> <p>1 (Exhibit 2 was marked for identification.)</p> <p>2 Q. Could you identify that document, please?</p> <p>3 A. This is a document marked Exhibit 2. And</p> <p>4 these are e-mails that I printed out from</p> <p>5 communication I had with Johnson & Johnson and Ethicon</p> <p>6 in regards to my interaction with them.</p> <p>7 Q. Okay. And have you produced these e-mails</p> <p>8 before to the plaintiffs at all, or is this the first</p> <p>9 time that you're producing this?</p> <p>10 A. This has been produced multiple times.</p> <p>11 This is the same batch of e-mails from a deposition I</p> <p>12 gave a few weeks ago on two different plaintiffs,</p> <p>13 Mrs. Ruiz and Mrs. Lehman, and also on the TVT-Secur</p> <p>14 product. These e-mails were also produced in a</p> <p>15 deposition and trial on plaintiff Colleen Perry.</p> <p>16 Q. And this is -- Exhibit 2 is dated</p> <p>17 November 12th, 2013, and it appears to be a</p> <p>18 procurement contract for your services with Johnson &</p> <p>19 Johnson; is that right?</p> <p>20 A. This is a new exhibit?</p> <p>21 Q. No, Exhibit 2. It's your contract for</p> <p>22 consulting with Johnson & Johnson.</p> <p>23 A. No, that's not the contract. The contract,</p> <p>24 I think, is the next document. That discussed maybe</p> <p>25 some contractual issues. And it was a notice that</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. Thank you.</p> <p>2 (Exhibit 4 was marked for identification.)</p> <p>3 Q. Exhibit 4 is a list of the cases in which</p> <p>4 you have testified or been deposed as an expert; is</p> <p>5 that correct?</p> <p>6 A. This is a five-year list of the most recent</p> <p>7 testimony and trial testimony -- deposition and trial</p> <p>8 testimony that I have participated in. The only thing</p> <p>9 it does not include is the recent deposition I gave,</p> <p>10 that you're aware of, in March of this year. So it's</p> <p>11 almost up to date. It just doesn't have the last list</p> <p>12 of depositions from March 2016.</p> <p>13 (Exhibit 5 was marked for identification.)</p> <p>14 Q. Great. And Exhibit 5, I've just marked, is</p> <p>15 your current CV or resume, correct?</p> <p>16 A. This is my CV or resume. It's been updated</p> <p>17 March 7th, 2016.</p> <p>18 Q. And then I'll mark as a group a series of</p> <p>19 communications from Butler Snow to you, one, two,</p> <p>20 three, four . . .</p> <p>21 (Exhibit 6 was marked for identification.)</p> <p>22 Q. Exhibit 6 are eight letters to you from</p> <p>23 Butler Snow; is that correct?</p> <p>24 A. That is correct.</p> <p>25 Q. And what are those letters?</p>

<p style="text-align: right;">Page 10</p> <p>1 A. When I receive documents from Butler and 2 Snow, there's a cover letter that is included in 3 either the USB that was sent to me, CD, DVD or paper 4 copy, so it's just a cover letter that came with the 5 package. 6 Q. And the last one -- the last cover letter 7 there is dated January of 2016. Do you think that's 8 the last time you received any materials from Butler 9 Snow? 10 A. No, I received materials since then, so in 11 addition to material that's been mailed to me, I have 12 received material electronically via zip drives, and 13 that's what I've included -- or excuse me, zip files, 14 so I've downloaded those files and put them on the 15 USB. 16 Q. Great. Thank you. 17 Do you have that USB with you? 18 A. I do. 19 Q. So you've brought with you, Doctor, two 20 USBs; is that right? 21 A. Correct. 22 Q. And what's your understanding of what is on 23 these USBs? 24 A. The USBs would be everything that I have 25 pertaining to TVT-O, including scientific articles,</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. And the reason that they're not in your 2 report or on your reliance materials is because you 3 received them after you wrote your report? 4 A. No, I think they were not critical to the 5 report, and so they weren't necessarily used to 6 formulate my opinions. I just tried to be as complete 7 as possible, so they were articles or PowerPoints that 8 pertained to TVT-O, but I didn't necessarily rely on 9 them or use them to compose my report. 10 MR. ZONIES: Okay. I'll mark these as 11 Exhibits 7 and 8. 12 (Exhibits 7 and 8 were marked for 13 identification.) 14 MR. KOOPMANN: Just for clarification, 15 Counsel, and so Greg knows, there may be some Prolift 16 materials -- I think there are some Prolift-related 17 materials on there as well, so you might mark them for 18 both depositions. 19 MR. ZONIES: That sounds great. Thank you. 20 THE WITNESS: Yeah, red one is the TVT-O, 21 and then the black one, I believe, is the Prolift. 22 Q. (By Mr. Zonies) Okay. So we'll say that 23 Exhibit 7 is primarily Prolift materials, and 24 Exhibit 8 is TVT-O. 25 A. The other way around.</p>
<p style="text-align: right;">Page 11</p> <p>1 PowerPoint presentations, videos, also media that I've 2 created. There's a video on TVT-O. There's an 3 abstract on TVT-O. So that was in response to the 4 notice of deposition. 5 Q. Thank you. 6 And I think you mentioned when you came in 7 that there may be some materials, including scientific 8 articles, on here that are not listed either in your 9 report or on your reliance materials; is that correct? 10 A. That's correct. 11 Q. Do you know, as you sit here, what those 12 might be? 13 A. There's probably quite a bit of 14 duplication, so a lot of those articles are articles 15 that I've collected personally over the years, so they 16 may duplicate with other articles that have been 17 provided to me for convenience. 18 Q. And do you know, as you sit here -- or is 19 there anything on here that you know, as you sit here 20 right now, that is not either on your reliance list or 21 in your report? 22 A. I know there are some documents, especially 23 Ethicon internal documents and PowerPoint 24 presentations, IFUs, patient brochures, things of that 25 matter.</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Other way around. 2 A. The one you have in your hand is TVT-O. 3 Q. The red one is TVT-O? 4 A. Correct. 5 Q. That is Exhibit 8. I've just marked that 6 as Exhibit 8. 7 A. Okay. 8 Q. You've also said that you've brought with 9 you a CD, or disk, as well; is that right, Doctor? 10 A. That is correct. 11 Q. And what's on there? 12 A. These articles, I believe, are also on the 13 USB. I can't be certain, but these articles were sent 14 to me on CD by Butler and Snow, these articles 15 pertaining to the Ethicon Gynecare pelvic mesh 16 litigation, specifically TVT-O, and I received this 17 July 2nd, 2015. 18 Q. So is it likely, since you received that in 19 July of 2015, that these materials are on your 20 reliance list or in your report? 21 A. I would say, most likely, the majority of 22 them I relied on. I received that CD, you know, 23 immediately before I was preparing the report. 24 (Exhibit 9 was marked for identification.) 25 Q. So I've marked this disk as Exhibit 9. And</p>

<p style="text-align: right;">Page 14</p> <p>1 it says on it "Butler Snow Ethicon Gynecare Pelvic 2 Mesh Litigation," and then in red ink it says "TVT-O." 3 Is that your red ink on there? 4 A. That's my handwriting, yes. 5 Q. Okay. And then "CD Received" in the red, 6 it says July 2nd, 2015; is that right? 7 A. Correct. 8 Q. And what else did you bring with you, 9 Doctor? 10 A. I have the most recent invoice that I've 11 prepared on TVT-O. 12 MR. ZONIES: Thank you. So I'll mark as 13 Exhibit 10 an invoice that says "Preparation of TVT-O 14 Report." 15 (Exhibit 10 was marked for identification.) 16 Q. And Doctor, can you tell me what that 17 represents, Exhibit 10? 18 A. This represents an invoice of the hours, 19 the rates and the total charges for preparation of the 20 TVT-O report. 21 Q. And does that invoice represent all of the 22 work you did up to and through the writing and 23 submission of your TVT-O expert report? 24 A. It does. 25 Q. And what is the total amount of time that</p>	<p style="text-align: right;">Page 16</p> <p>1 A. And some additional ones as well. 2 Q. What additional ones? 3 A. Specific to slings? 4 Q. Yes. 5 A. So just to summarize -- 6 MR. KOOPMANN: I don't want him to talk 7 about things that he's consulting on that are 8 confidential yet. 9 MR. ZONIES: Okay. 10 MR. KOOPMANN: What he's disclosed -- what 11 Ethicon has disclosed are the TVT, TVT-O and TVT-Secur 12 reports. 13 MR. ZONIES: Understood. 14 Q. (By Mr. Zonies) So Doctor, we've received 15 three TVT sling reports, one for O, one for R, and one 16 for S. 17 My question is, which of those three, R, O 18 or S, did you write first? 19 A. TVT-R. 20 Q. The Retropubic. And as you've discussed, 21 the first, about, 20 pages of your report is very 22 similar regarding those three products, TVT-R, O and 23 S; is that right? 24 MR. KOOPMANN: Object to form. 25 A. It's regards to the history of</p>
<p style="text-align: right;">Page 15</p> <p>1 you spent researching and writing your TVT-O report? 2 A. Sixteen hours. 3 Q. And you billed for that 16 hours at 4 different prices depending on the task that you were 5 doing, correct? 6 A. Correct. 7 Q. And actually, you only billed for 16 hours 8 for preparation of your report at \$500 an hour 9 totaling \$8,000, correct? 10 A. Correct. 11 Q. And that's the total amount of time, 16 12 hours, that you spent researching, writing, 13 proofreading, and signing your expert witness report 14 for TVT-O in this litigation, correct? 15 A. Correct. But I would like to also add that 16 before I prepared the TVT-O, I prepared TVT. And 17 there's a lot of similarity between the two reports, 18 so I didn't include those hours of preparation of this 19 since they were included in other invoices. So in 20 terms of writing the history of incontinence and the 21 options, and so maybe 40, 50 percent of that report 22 had come from a previous report that I had authored. 23 Q. And so you have authored, regarding Ethicon 24 slings, three reports, a TVT-Retropubic, TVT-Obturator 25 and TVT-Secur report, correct?</p>	<p style="text-align: right;">Page 17</p> <p>1 incontinence, my background, qualifications. Those 2 are the things that are similar. The product-specific 3 stuff is different. 4 Q. (By Mr. Zonies) Okay. And in your 5 reports -- and we can go through this in detail later, 6 but, in general, in your reports, you talk about your 7 qualifications, then you talk about the history of 8 incontinence and various treatments for it, and then 9 you have a history of TVT-Retropubic where you discuss 10 Ohmsten in each of the reports, correct? 11 A. That's correct. 12 Q. And that, generally, are the sections that 13 are the same throughout the three reports, correct? 14 A. Correct. 15 Q. And it would be your testimony that the 16 billing -- the time that you spent writing those 17 sections, we'll see the invoice for that time 18 primarily in the TVT-Retropubic deposition next week, 19 correct? 20 A. Correct. 21 Q. So the 16 hours working on TVT-O -- on your 22 TVT-O report that are reflected in Exhibit 10, those 23 16 hours are focused primarily on the TVT-O-specific 24 section of your TVT-O report, correct? 25 A. Correct.</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. Is there anything else that you brought 2 with you today, Doctor, other than the binder? I'll 3 get to that last.</p> <p>4 A. This is not -- this is part of my binder, 5 but not punched, three-hole punched, is just a 6 bibliography of the articles in my TVT-O report. 7 That's just compiled a little bit different than -- 8 the footnotes are on each page of this report, and I 9 also like to have them just separate and organized and 10 alphabetized, so that's something that I had prepared 11 separately.</p> <p>12 (Exhibit 11 was marked for identification.)</p> <p>13 Q. So what I'm marking as Exhibit 11, Doctor, 14 is a document that is eight pages long and entitled 15 "TVT-O" at the top, correct?</p> <p>16 A. Correct.</p> <p>17 Q. And this appears to be an alphabetical 18 listing of various studies, correct?</p> <p>19 A. Correct.</p> <p>20 Q. And is it your testimony that the studies 21 that are listed in Exhibit 11 are all studies that are 22 cited in the body of your report?</p> <p>23 A. That's correct.</p> <p>24 Q. And then the -- after the studies, there 25 are a number of other documents listed. Can you</p>	<p style="text-align: right;">Page 20</p> <p>1 The reliance list that you provided with 2 your TVT-O report, is that the same reliance list that 3 you also provided with your TVT-R and O report -- S 4 report?</p> <p>5 A. No, this is unique to this report and this 6 deposition.</p> <p>7 MR. ZONIES: Doctor, I'm marking as 8 Exhibit 12 your expert report entitled "Expert 9 Overview of TVT-Obturator" that was provided to us in 10 this case.</p> <p>11 (Exhibit 12 was marked for identification.)</p> <p>12 Q. Is Exhibit 12 your expert report in this 13 litigation for the TVT-Obturator?</p> <p>14 A. This is a 53-page document. It looks to be 15 the same exact report, although without reading every 16 word of it, I can't be a hundred percent certain, but 17 to my best knowledge, it looks to be the same.</p> <p>18 Q. And I'll represent to you, Doctor, that 19 Exhibit 12 is what was provided to us as an expert 20 report. If you do notice any differences between that 21 and what you have in your binder in front of you, just 22 let me know, and we'll talk about that, okay?</p> <p>23 A. Okay.</p> <p>24 Q. This Exhibit 12 was executed by you and 25 dated February 26, 2016, is that right, on page 53?</p>
<p style="text-align: right;">Page 19</p> <p>1 describe what those documents are?</p> <p>2 A. These documents are documents that don't 3 have an author's name on them, so this list is 4 compiled in alphabetical order based on first author, 5 and these nine or so other documents don't have a lead 6 author on them. So that's why they were listed at the 7 end of the report.</p> <p>8 Q. Is it your testimony that those documents 9 are also documents that are included in the body of 10 your report?</p> <p>11 A. Yes.</p> <p>12 Q. And then you also brought with you a large 13 binder, Doctor?</p> <p>14 A. Yes.</p> <p>15 Q. And what's in that binder?</p> <p>16 A. This binder is my expert overview of 17 TVT-Obturator.</p> <p>18 Q. Your report?</p> <p>19 A. My report.</p> <p>20 Q. Okay.</p> <p>21 A. And it has my reliance list. And then the 22 next 32 sections are the articles that are cited in 23 this report.</p> <p>24 Q. The reliance list that you have in front of 25 you, Doctor -- well, strike that.</p>	<p style="text-align: right;">Page 21</p> <p>1 A. February 26, 2016, that's correct.</p> <p>2 Q. And other than a copy of your expert report 3 in the binder, you said that there are 32 tabs in the 4 binder. What are in those 32 tabs?</p> <p>5 A. So they correspond to the footnotes in the 6 report. So for instance, Footnote Number 1 is from 7 Albo, Burch colposuspension. Then if you go to tab 1, 8 it has that article, "Burch Colposuspension" by 9 Michael Albo.</p> <p>10 Q. And your expert report has more than 32 11 footnotes. You have the other two binders here that 12 cover the rest of the footnotes, correct?</p> <p>13 A. Correct.</p> <p>14 Q. So Doctor, if we take a look at Exhibit 12, 15 your expert report in this case, the first section is 16 called "Background and Qualifications"; do you see 17 that?</p> <p>18 A. Yes.</p> <p>19 Q. And this is a section, for example, that 20 you would have originally written for the 21 TVT-Retropubic report and largely reproduced here for 22 your TVT-O report, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And that section, Section 1, "Background 25 and Qualifications, "goes for pages 1, 2, and a</p>

<p style="text-align: right;">Page 22</p> <p>1 portion of 3 until a section called "Urinary 2 Incontinence," correct? 3 A. Correct. 4 Q. And then if you go through until page 5, 5 the third section is called "Treatment Options For 6 SUI," correct? 7 A. Yes. 8 Q. Section IV on page 10 is entitled "TVT and 9 the Midurethral Sling," correct? 10 A. Correct. 11 Q. And that section runs until the top of page 12 20, correct? 13 A. Correct. 14 Q. Would it be your testimony, Doctor, that 15 those first 20 pages of your report are largely the 16 same as what you wrote for your TVT-R report? 17 A. I would say yes, 70, 80 percent the same. 18 There are some additional paragraphs, or maybe some 19 new information or new titles or appointments or 20 things, accomplishments that I have, so I would say, 21 for the most part, it's very similar. 22 Q. Great. And then on page -- 23 A. But the biggest difference would be Section 24 B, "Relative Surgical Experience." With each report, 25 the last paragraph, I try to include as much detail as</p>	<p style="text-align: right;">Page 24</p> <p>1 A. Yes. 2 Q. And that's the year that it first came to 3 market, correct? 4 A. I'm not a hundred percent sure that that's 5 the year I started using it. 6 Q. You've described yourself before as an 7 early adopter. Would it make sense for you to have 8 started using TVT-O when it first came out? 9 A. Yes. 10 Q. Prior to 2004, had you been using any sling 11 device to treat stress urinary incontinence? 12 A. Yes. 13 Q. Were you using any sling device that 14 utilized the obturator approach? 15 A. No. 16 Q. Prior to 2004, all of your sling procedures 17 were retropubic procedures? 18 A. Correct. 19 Q. And from 2004 until 2007, the TVT-Obturator 20 was the primary device you used for treatment of 21 stress urinary incontinence in your practice? 22 A. Yes. 23 Q. So over that three-year period, did you use 24 any other polypropylene mesh slings for the treatment 25 of stress urinary incontinence other than the</p>
<p style="text-align: right;">Page 23</p> <p>1 I can on my experience with that specific product. 2 Q. And you're talking about on page 3, the 3 paragraph that begins with, "I used TVT-Obturator from 4 2004 to 2010"? 5 A. That's correct. 6 Q. And then on page 20, you actually start 7 with a Section B, which is "TVT-Obturator History." 8 And that's all new material as compared to your TVT-R 9 report, correct? 10 A. That's correct. 11 Q. So let's talk about that one paragraph 12 that's different from your R report on page 3. Do you 13 have that in front of you? 14 A. I do. 15 Q. Doctor, on page 3 of your expert report, 16 you state that "I used the TVT-Obturator from 2004 17 until 2010, and TVT-Obturator was the most commonly 18 performed procedure for SUI in my practice from 2004 19 to 2007." Is that what you wrote? 20 A. That's what I wrote. 21 Q. And is that correct? Is that accurate as 22 you're sitting here today? 23 A. Yes. 24 Q. So you began to use the TVT-Obturator 25 device in 2004?</p>	<p style="text-align: right;">Page 25</p> <p>1 TVT-Obturator? 2 A. Yes. 3 Q. What else did you use in that time frame? 4 A. With respect to mesh slings? 5 Q. Yes. 6 A. I used the TVT, just what was known as TVT, 7 which was a retropubic system. Some people call it 8 the TVT-Classic or TVT-Retropubic. 9 Q. So in the period between 2004 and 2007, you 10 only used Ethicon products for the treatment of stress 11 urinary incontinence if you were using a mesh sling, 12 correct? 13 A. For the most part. There was a transition 14 period I was using products from American Medical 15 Systems before 2004, and so there may have been some 16 overlap with those products. And then depending on 17 what hospital I operated at, so for instance at the VA 18 Hospital, they may not have had the Ethicon products, 19 just the American Medical System products, so I used 20 their product. 21 Q. Have you ever used the AMS Obturator sling? 22 A. I don't believe so. I've used the AMS 23 Sparc, BioArc, MiniArc and MiniArc Precise with 24 respect to sling surgery. 25 Q. And are those all retropubic slings?</p>

<p style="text-align: right;">Page 26</p> <p>1 A. So the BioArc and the Sparc were retropubic 2 slings, and then the MiniArc is a transobturator 3 mini-sling. It anchors into the obturator internus. 4 Q. And when did you start to use the MiniArc? 5 A. I would have to go back and look at my 6 notes, but it was probably sometime in and around when 7 it first became available, 2008, maybe 2009. I don't 8 know the exact date. 9 Q. When you began to use -- strike that. 10 So between 2004 and 2007, you primarily used 11 the TVT-Retropubic and the TVT-Obturator slings, 12 correct? 13 A. Correct. 14 Q. In 2007, that changed, correct? 15 A. Correct. 16 Q. What changed in 2007? 17 A. I continued to do TVT-Obturator, but I did 18 TVT-Secur more commonly after that date. So I had 19 done primarily TVT-Obturator, let's say, maybe 70, 80 20 percent of the mesh slings I did, and then gradually 21 that was replaced, for the most part, by TVT-Secur. 22 But there were some patients that I still preferred 23 TVT-Obturator on. 24 Q. And so in the time frame between 2007 and 25 2010, is it fair to say that the TVT-Secur was the</p>	<p style="text-align: right;">Page 28</p> <p>1 it performed. 2 Q. Did you feel that the TVT-Abbrevio had any 3 clinical benefits over the TVT-Obturator? 4 A. The biggest benefit that I noticed was 5 there was less transient groin pain with the 6 TVT-Abbrevio. 7 Q. So the primary difference in your practice 8 between the TVT-Abbrevio and the TVT-O was you actually 9 noticed a decrease in thigh pain with the use of the 10 Abbrevio as compared to the O, correct? 11 MR. KOOPMANN: Object to form. 12 A. That's incorrect. 13 Q. (By Mr. Zonies) I'm sorry. Tell me what 14 benefit, if any, you felt that you realized from using 15 the Abbrevio as compared to the O. 16 A. Well, what I had said was that it was 17 transient groin pain, so there was improvement in 18 transient groin pain. But if you look at the amount 19 of groin pain they had at three months or at a year, 20 it was very similar. And that's what the literature 21 shows as well. And my experience was similar. 22 Q. So you chose to use the Abbrevio instead of 23 the O, correct? 24 A. Correct. 25 Q. One of the reasons that you said that you</p>
<p style="text-align: right;">Page 27</p> <p>1 primary sling you were using? 2 A. Approximately those dates. 3 Q. And then so in that time frame between 2007 4 and 2010, how many TVT-Obtulators do you think you 5 utilized? 6 A. Not that many. Probably less than 20. 7 Q. And then in 2010 you stopped using 8 TVT-Obturator altogether. Is that because the Abbrevio 9 came out? 10 A. Correct. 11 Q. Once the TVT-Abbrevio came out, did you stop 12 using TVT-Obturator full-length slings altogether? 13 A. I believe that's so. There may have been 14 an exception here and there, but I can't think of an 15 instance where I would have preferred to use that over 16 TVT-Abbrevio. 17 Q. And why was that? Why did you prefer the 18 TVT-Abbrevio over the TVT-Obturator? 19 A. I thought they were very similar products. 20 And as I mentioned earlier in other depositions, I do 21 like trying new products. I tend to be on that first 22 wave. And TVT-Abbrevio was something that I was 23 introduced to very early on, and I was involved in a 24 video regarding TVT-Abbrevio. And to me, it just 25 seemed very similar to TVT-Obturator. And I liked how</p>	<p style="text-align: right;">Page 29</p> <p>1 chose to use the Abbrevio instead of the O is because 2 you felt that with the Abbrevio, your patients had less 3 transient groin pain when you used the Abbrevio as 4 compared to the O, correct? 5 A. Correct. 6 Q. And so you felt that the Abbrevio was a 7 better product than the O for that reason, correct? 8 MR. KOOPMANN: Object to form. 9 A. I felt that it provided less pain for the 10 patient transiently, so I was able to discharge them 11 the same day, send them home on less pain pills. They 12 had an earlier return to activity and to employment, 13 and so that was an advantage. 14 Q. (By Mr. Zonies) And those advantages of 15 the TVT-Abbrevio over the TVT-Obturator, those, as you 16 said, are recognized in the literature as well, 17 correct? 18 A. Yes. If you look at the Hinoul study, 19 de Leval study, there was a few early studies on -- 20 that did demonstrate less transient groin pain, but 21 the benefits evened out by three months in those 22 studies. So there wasn't a long-term benefit in terms 23 of reduced groin pain. 24 Q. But that was certainly a benefit that you 25 could bring to your patients, correct? You could say</p>

<p style="text-align: right;">Page 30</p> <p>1 to your patients -- well, let me ask you, Doctor, when 2 you were discussing with your patients the various 3 options for treatment of their stress urinary 4 incontinence, did you discuss with them both the 5 Abbrevio and the TVT-Obturator as options? 6 A. I discussed all the midurethral slings, and 7 I discussed all the options of stress urinary 8 incontinence with my patients, yes. 9 Q. And when you were discussing, in 10 particular, the use of the Abbrevio as compared to the 11 full-length TVT-O, you told them that there were 12 certain benefits that you were seeing in your practice 13 associated with using the Abbrevio, correct? 14 A. Correct. 15 Q. And the benefits you told your patients 16 were that, one, you were seeing that -- and you 17 believed they would have less transient groin pain if 18 you used the Abbrevio as compared to the O, correct? 19 A. Correct. 20 Q. And you also told them that your experience 21 was that your patients would have a shorter 22 convalescence from the procedure if you used the 23 Abbrevio as compared to the O, correct? 24 A. Correct. 25 Q. That they would be able to return to work</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. So would it be fair to say an index patient 2 is what one would think of as a common patient that 3 ob/gyns are seeing in their practice who has stress 4 urinary incontinence? 5 A. It would be unique to the practice. I'm 6 not an ob/gyn, but from my discussions with ob/gyn 7 colleagues, yes, that's typically the patient they 8 see. 9 Q. So if we're talking about that typical 10 patient that's seen by a physician trying to determine 11 how to treat stress urinary incontinence, in that 12 situation, you would choose, and chose in your 13 practice, to use the TVT-Abbrevio as compared to the 14 TVT-Obturator, correct? 15 A. Yes. 16 Q. And that's, in part, for the reasons that 17 we just discussed, that the beneficial outcomes that 18 you would see related to pain management and being 19 able to return to activities more quickly with the 20 TVT-Abbrevio as compared to the TVT-O, correct? 21 A. Correct. 22 Q. Is there any reason for an index patient or 23 a typical patient where you would choose the 24 TVT-Obturator over the Abbrevio? 25 A. If the patient requested it. Oftentimes</p>
<p style="text-align: right;">Page 31</p> <p>1 more quickly if you used the Abbrevio as compared to 2 the O, correct? 3 A. Correct. 4 Q. And that they would have less time -- they 5 would be able to return to activities and the 6 activities of daily living more quickly if you used 7 the Abbrevio as compared to the TVT-O, correct? 8 A. Correct. 9 Q. Did you find that there was any -- you've 10 described an index patient before; is that right, 11 Doctor? 12 You know what the definition of an index 13 patient is, or what your definition of an index 14 patient is? 15 A. I can tell you what my definition is. 16 Q. What is an index patient? 17 A. An index patient is a term that has been 18 described by the American Urologic Association in 19 their SUI guidelines. And that patient is a patient 20 that is a more straightforward patient, so they have 21 genuine stress urinary incontinence and they don't 22 have any complicating factors. They tend to have 23 low-volume incontinence. So that's a patient that 24 people in community practices in urology and 25 urogynecology and female pelvic medicine see commonly.</p>	<p style="text-align: right;">Page 33</p> <p>1 patients have done a significant amount of research. 2 Maybe they have a friend or family member that have 3 had a certain product and have had a good outcome, and 4 oftentimes they come in requesting that. And if it 5 seems reasonable, I explain to them the risks and 6 benefits of both procedures and let them decide. So 7 there would be a few exceptions, as I mentioned, you 8 know, between 2007 and present. 9 Q. But from your clinical perspective, your 10 preference is for the Abbrevio over the TVT-Obturator, 11 correct? 12 MR. KOOPMANN: Object to form. 13 A. Again, it would depend on the unique 14 patient, but yeah, I transitioned from TVT-Obturator 15 to TVT-Abbrevio in 2010. And I haven't transitioned 16 back, or made any changes in that. 17 Q. (By Mr. Zonies) So Doctor, are there any 18 other benefits that you saw in your clinical practice 19 or that you believe exist for using the Abbrevio as 20 compared to the TVT-O? 21 A. No, that was it, just the transient 22 perioperative benefits that I noticed. 23 Q. You treat -- a large part of your practice 24 is treating complications that women have suffered 25 from mesh implants, correct?</p>

<p style="text-align: right;">Page 34</p> <p>1 MR. KOOPMANN: Object to form.</p> <p>2 A. It's part of my practice, yes.</p> <p>3 Q. (By Mr. Zonies) And in treating women who</p> <p>4 have slings and complications from those slings, do</p> <p>5 you believe there's a benefit to treating a woman who</p> <p>6 has an Abbrevio as compared to a TVT-Obturator?</p> <p>7 A. No.</p> <p>8 Q. Do you believe that it is -- strike that.</p> <p>9 Have you ever removed a TVT-Abbrevio?</p> <p>10 A. Yes.</p> <p>11 Q. Have you ever removed a TVT-Obturator?</p> <p>12 A. Yes.</p> <p>13 Q. Can you describe the differences in the</p> <p>14 outcomes for those procedures?</p> <p>15 A. The procedures are very similar. It just</p> <p>16 depends on what you're removing and where their</p> <p>17 complaint is. The overwhelming majority of them, we</p> <p>18 would remove part of the vaginal portion of the mesh,</p> <p>19 so that's the part of the mesh lying below the</p> <p>20 midurethra, maybe extending towards the obturator</p> <p>21 internus. But it would be unique to the patient based</p> <p>22 upon where their pain was located at. But the</p> <p>23 procedures, the outcomes, it would be very similar,</p> <p>24 from my recall. I've never looked at it formally,</p> <p>25 though.</p>	<p style="text-align: right;">Page 36</p> <p>1 A. 12 centimeters.</p> <p>2 Q. So when you remove an Abbrevio, how much of</p> <p>3 that 12 centimeters are you typically removing?</p> <p>4 A. Typically somewhere around 5 to 6</p> <p>5 centimeters.</p> <p>6 Q. And so leaving behind roughly 6 centimeters</p> <p>7 of mesh, correct?</p> <p>8 A. Correct.</p> <p>9 Q. And when you remove a TVT-O, how much mesh</p> <p>10 do you typically leave behind?</p> <p>11 A. Well, we remove the same amount, 5 to 6</p> <p>12 centimeters, and if the average TVT-O is 18, then it</p> <p>13 would be around 12 centimeters.</p> <p>14 Q. So when you remove a TVT-O, you're leaving</p> <p>15 behind roughly twice the mesh as when you remove a</p> <p>16 TVT-Abbrevio; is that fair?</p> <p>17 A. Sounds about right.</p> <p>18 Q. Is that a discussion that you have with</p> <p>19 your patients when removing a mesh?</p> <p>20 A. No.</p> <p>21 Q. Is that a factor that you considered when</p> <p>22 you decided it use the TVT-Abbrevio instead of the</p> <p>23 TVT-O?</p> <p>24 A. No.</p> <p>25 Q. In 2004, Doctor, you started to use the</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. When you treat -- is the Abbrevio considered</p> <p>2 a mini-sling?</p> <p>3 A. It's not.</p> <p>4 Q. Does the Abbrevio go through the obturator</p> <p>5 membrane?</p> <p>6 A. It does.</p> <p>7 Q. Does it go through the obturator muscles</p> <p>8 internus?</p> <p>9 A. Both the internus and externus.</p> <p>10 Q. When you remove an Abbrevio, do you leave</p> <p>11 mesh behind, typically?</p> <p>12 A. In most cases, yeah. 95 percent of the</p> <p>13 time we would leave mesh behind, yes.</p> <p>14 Q. When you remove a TVT-Obturator, do you</p> <p>15 leave behind more mesh than you do when you remove a</p> <p>16 TVT-Abbrevio, typically?</p> <p>17 A. Typically, yes.</p> <p>18 Q. And that's because the TVT-Obturator has</p> <p>19 more mesh already in the body, correct?</p> <p>20 A. The TVT-Obturator is a longer sling. It's</p> <p>21 45 centimeters out of the box. What typically ends up</p> <p>22 in the average patient is somewhere around 18</p> <p>23 centimeters.</p> <p>24 Q. And what typically ends up in the patient</p> <p>25 with an Abbrevio?</p>	<p style="text-align: right;">Page 37</p> <p>1 TVT-Obturator sling, correct?</p> <p>2 A. Correct.</p> <p>3 Q. Were you aware that in that same time frame</p> <p>4 in 2004, that Ethicon was working with Dr. de Leval to</p> <p>5 address the groin and thigh pain that they were seeing</p> <p>6 with the TVT-O sling?</p> <p>7 A. I was not aware of what interactions they</p> <p>8 were having with Dr. de Leval.</p> <p>9 Q. Were you aware that in early 2004 that</p> <p>10 Ethicon was meeting with Dr. de Leval to address --</p> <p>11 strike that.</p> <p>12 Were you aware in 2004 that Ethicon was</p> <p>13 meeting with Dr. de Leval to discuss using a shorter</p> <p>14 sling to lessen the thigh and groin pain that they</p> <p>15 were seeing with the TVT-O device?</p> <p>16 MR. KOOPMANN: Object to form.</p> <p>17 A. Are you asking me if I was aware of that in</p> <p>18 2004?</p> <p>19 Q. (By Mr. Zonies) First I'd like to talk</p> <p>20 about, yes, were you aware of that in 2004?</p> <p>21 A. No.</p> <p>22 Q. So for the period of time from 2004 until</p> <p>23 you switched to the TVT-Abbrevio, you weren't aware,</p> <p>24 during that time frame, that Ethicon knew there was an</p> <p>25 issue with groin and thigh pain with the TVT-O and</p>

<p style="text-align: right;">Page 38</p> <p>1 were having discussions with de Leval about using a 2 shorter sling to lessen that groin and thigh pain? 3 MR. KOOPMANN: Object to form. 4 A. I've only become aware recently of the 5 discussions. I have been an expert for the last few 6 years, and I've seen internal documents. And I've 7 reviewed studies from de Leval comparing the 8 abbreviated version of TVT-O, so I wouldn't say until 9 2009 or 2010 did I become aware of TVT-Abbrevio, or 10 whatever it was called, its prototype. 11 Q. (By Mr. Zonies) So would it be fair to 12 say, Doctor, that given the benefits that you saw with 13 the transient groin pain associated with using the 14 Abbrevio, that had the Abbrevio been introduced in 2004, 15 you likely would have gone straight to the Abbrevio 16 because it had benefits for your patients? 17 A. Not necessarily. 18 Q. Why not? 19 A. You know, it's a decision. Any time a new 20 product comes out, there's a lot of factors that go 21 into the decision, and so I have to look at all of 22 those factors before I make that decision. 23 Q. But it's certainly clear that at the time 24 the TVT-Abbrevio came to market, you stopped using the 25 TVT-O, correct?</p>	<p style="text-align: right;">Page 40</p> <p>1 A. As I stated earlier, I felt that there was 2 a benefit in having less transient groin pain. 3 Q. And had the Abbrevio been available for your 4 use earlier in 2009 or 2008 or 2007, and you saw that 5 same benefit for your clients, isn't it likely that 6 you would have made the switch to the Abbrevio earlier? 7 A. There's a possibility. I can't say for 8 sure. I saw some of the literature on TVT-Abbrevio. I 9 mentioned earlier that I was interested in trying new 10 products. There was some reasons there why I switched 11 to TVT-Abbrevio. 12 Q. And what were those reasons? 13 A. As I stated, it was a new product. I like 14 trying new products. It was proposed as having less 15 pain for the patient in the transient postop period. 16 Dr. Hinoul had done some work on that. Dr. de Leval 17 had looked at the TVT-O and the modified TVT-O, and so 18 I was interested in trying TVT-O. And once I started 19 using the product, it performed very well in my hands. 20 Q. And you found, actually, that you got that 21 clinical benefit of less pain for your clients. They 22 could return to activities and work more quickly, and 23 had a better convalescence when you used the Abbrevio 24 as compared to the O, correct? 25 MR. KOOPMANN: Object to form.</p>
<p style="text-align: right;">Page 39</p> <p>1 A. Incorrect. 2 Q. Doctor, is it true that when the 3 TVT-Abbrevio came to market, you largely stopped using 4 the TVT-Obturator device and began using the 5 TVT-Abbrevio? Correct? 6 A. Correct. 7 Q. And that, as we have discussed, was because 8 you saw certain benefits for your patients when you 9 used the TVT-Abbrevio, the -- as you said, the 10 abbreviated version of the TVT-O, correct? 11 MR. KOOPMANN: Object to form. 12 A. Can you repeat the question? 13 Q. (By Mr. Zonies) Sure. 14 You started to use the TVT-Abbrevio instead 15 of the O because you saw benefits for your patients 16 particularly around the transient groin pain when you 17 used the Abbrevio instead of the O, correct? 18 MR. KOOPMANN: Same objection. 19 A. Incorrect. 20 Q. (By Mr. Zonies) Abbrevio has two Bs, right? 21 A. Yes. A-b-b-r-e-v-o. 22 Q. Doctor, in your practice, you continued to 23 use the TVT-Abbrevio instead of the TVT-Obturator in 24 part because you felt there was a clinical benefit for 25 your patients regarding pain; is that correct?</p>	<p style="text-align: right;">Page 41</p> <p>1 A. I would say correct. 2 Q. (By Mr. Zonies) And that's a benefit that 3 you would have wanted to bring to your clients as soon 4 as possible, correct -- "clients," sorry. 5 That's a benefit that you would have wanted 6 to bring to your patients as soon as possible, 7 correct? 8 A. Not necessarily. 9 Q. Do you want your patients to suffer pain 10 unnecessarily? 11 A. I don't. 12 Q. It's a benefit for them to have less pain, 13 isn't it? 14 A. The surgical decision-making is a balance, 15 okay, between efficacy and safety. And so we have to 16 factor all of those things in when making our 17 decisions. 18 Q. But you made the decision clearly in your 19 practice that the Abbrevio was preferred over the O, 20 correct? 21 MR. KOOPMANN: Object to form. 22 A. I evolved to that decision. Usually we try 23 new products, and we make a decision if we want to 24 persist with them or go back to the product that we 25 were using previous.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q. (By Mr. Zonies) And you chose to evolve 2 and stay with, as you said, the TVT-Abbrevo over the 3 TVT-O since 2010, primarily, correct? 4 A. That's correct. 5 Q. And that's a decision you made because you 6 felt there were -- that the Abbrevo was a better 7 product for your patients, correct? 8 MR. KOOPMANN: Object to form. 9 A. I wouldn't use the word "better." 10 Q. (By Mr. Zonies) It had benefits for your 11 patients particularly around groin pain and being able 12 to return to activities more quickly, correct? 13 A. Correct. 14 Q. Those are benefits you would like to bring 15 to your patients as soon as they're available to bring 16 to them, correct? 17 A. Incorrect. I stated earlier, you have that 18 balance, so if someone, you know, gets better sooner 19 but doesn't have the same efficacy long-term, then 20 that's not necessarily something I want to bring to 21 patients. 22 Q. But you made the choice -- as you sit here 23 today, you believe that the Abbrevo has similar 24 efficacy to the TVT-Obturator, correct? 25 A. Correct.</p>	<p style="text-align: right;">Page 44</p> <p>1 over a TVT-Abbrevo? 2 MR. KOOPMANN: Object to form. 3 A. Sitting here today with the information and 4 experience I had with both products, no, there'd be no 5 reason I would use a TVT-O over the TVT-Abbrevo unless 6 the patient had requested that. 7 Q. (By Mr. Zonies) When do you think the last 8 time was that you used a TVT-Obturator? 9 A. I would think somewhere around maybe 2011 10 or 2012. I don't know the exact date. I know in 2010 11 that's when I made the switch primarily. Again, there 12 may have been some overlap or some differences based 13 on what hospital I was at. 14 Q. And you, in fact, became a key opinion 15 leader for TVT-Abbrevo; is that right? 16 A. I don't know how I was characterized by 17 Ethicon, but I was an early adopter of TVT-Abbrevo. I 18 did the video on TVT-Abbrevo. I did professional 19 education events on TVT-Abbrevo. 20 Q. And you created a training video for the 21 TVT-Abbrevo that Ethicon asked you to do, correct? 22 A. I would say "create" is too strong of a 23 word. I partnered with them on that project. 24 Q. So you partnered with Ethicon to create a 25 training video for the TVT-Abbrevo, correct?</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. And it has less pain associated with its 2 use, correct? 3 MR. KOOPMANN: Object to form. 4 A. Less transient groin pain, correct. 5 Q. (By Mr. Zonies) And it allows your 6 patients to return to work more quickly, correct? 7 A. Correct. 8 Q. It allows your patients to return to 9 activities of daily living more quickly, correct? 10 A. Correct. 11 Q. Those are all benefits on complications 12 with similar efficacy, correct? 13 A. Can you restate that? That word 14 "complications," I'm not sure what you mean by that. 15 Q. Sure. 16 So in your expert opinion, the Abbrevo has 17 similar efficacy to the TVT-O, correct? 18 A. Correct. 19 Q. And the Abbrevo has added benefits as 20 compared to the TVT-O primarily around transient groin 21 pain, correct? 22 A. Correct. 23 Q. And so is there any reason, as you sit here 24 today, that you would choose, from a clinical 25 perspective, to use a TVT-Obturator full-length sling</p>	<p style="text-align: right;">Page 45</p> <p>1 A. They approached me and asked me if they 2 could film one of my cases on TVT-Abbrevo. 3 Q. And then Ethicon, as you know, used that 4 video to market the TVT-Abbrevo device, correct? 5 A. I don't know what they did with it. I gave 6 them permission to use the video content and edit it 7 and use it as they see fit. 8 Q. And you also -- and Ethicon compensated you 9 for making that video, correct? 10 A. Correct. 11 Q. You also were -- Ethicon partnered with you 12 to do professional education for the TVT-Abbrevo, 13 correct? 14 A. Yes. 15 Q. And that entailed your traveling to events 16 to discuss the benefits of the TVT-Abbrevo with other 17 doctors, correct? 18 A. Very limited. As I mentioned earlier, my 19 contract and my consulting with them ended around 20 2011, so there was a brief period of time there, less 21 than a year, that I did professional education. My 22 professional education with TVT-Abbrevo centered 23 largely around that video. 24 Q. And in that video and at these various 25 professional education events, you would discuss how</p>

<p style="text-align: right;">Page 46</p> <p>1 you felt that the Abbrevio had advantages over the 2 TVT-Obturator, correct?</p> <p>3 A. I don't remember discussing risks and 4 benefits. It was primarily on how to do the 5 procedure, how it's performed, that that was the focus 6 of the video.</p> <p>7 Q. Do you recall that when you made those 8 presentations, you would actually inform physicians 9 that you were teaching that the Abbrevio, in your 10 hands, had less transient groin pain and allowed your 11 patients to return to work and activities more quickly 12 and, therefore, you felt it was a better procedure 13 than TVT-O?</p> <p>14 A. I don't recall saying that.</p> <p>15 Q. Might you have said that?</p> <p>16 A. I don't know. It was -- when I was an 17 early adopter, usually I liked to do a certain number 18 of cases before I speak very strongly about the 19 product until I gain some personal experience with the 20 device, so I don't think I would have necessarily said 21 that, since I had just started using the product.</p> <p>22 Q. Now, on page 20 of your expert report, 23 Doctor, there's a section entitled "TVT-Obturator 24 History"; do you see that?</p> <p>25 A. I do.</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. So you think that reference is the 2 TVT-Obturator as compared to the Abbrevio, correct?</p> <p>3 A. Correct.</p> <p>4 Q. So when you say that "Anatomic studies have 5 shown that the mesh traverses less muscular 6 structures," what you mean is that -- why is that 7 important, that the mesh traverses less muscular 8 structures?</p> <p>9 A. I think the thought is that if there's less 10 structures that it traverses, then there's a potential 11 to have less pain.</p> <p>12 Q. And from your experience, in fact, because 13 the TVT-Abbrevio traverses less muscular structures 14 than does the TVT-Obturator, you actually have 15 experience that your patients have less pain, correct?</p> <p>16 MR. KOOPMANN: Object to form.</p> <p>17 A. They have less transient groin pain.</p> <p>18 Q. (By Mr. Zonies) And that is a benefit that 19 the Abbrevio has over the TVT-Obturator, correct?</p> <p>20 A. Correct.</p> <p>21 Q. Why do you think it's important to note in 22 your report that the mesh lies, on average, 2 to 3 23 centimeters from the obturator nerve when placed? Why 24 is that important?</p> <p>25 A. What was emphasized is that you want to</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. And in the last sentence there, you say, 2 "Anatomic studies have shown that the mesh traverses 3 less muscular structures and lies on average 2 to 3 4 centimeters from the obturator nerve when placed 5 properly," and you cite the Hinoul; is that right?</p> <p>6 A. I think what it is doing is comparing, 7 yeah, the early TVT-O procedure to the outside-to-in 8 obturator procedures. So I think, you know, when this 9 makes that comment, that's what it's comparing itself 10 to, the inside-out versus the outside-in.</p> <p>11 Q. So --</p> <p>12 A. I'm sorry. Let me take that back. 13 Compared to the TVT product.</p> <p>14 Q. Okay. And that -- you're predicting my 15 questions on this part, which is, on page 20 of your 16 report, Doctor, you say, "Anatomic studies have shown 17 that the mesh traverses less muscular structures." 18 When you say that in your report, you're 19 saying that a TVT-Obturator mesh traverses less 20 muscular structures than does the TVT-Retropubic?</p> <p>21 A. No, that's not correct. Let me restate 22 that. I think that that comment is a comment with 23 reference to comparison between the TVT-Obturator and 24 the modified TVT-Obturator. That's what that 25 reference is for.</p>	<p style="text-align: right;">Page 49</p> <p>1 stay medial in the foramen, or away from the vessels 2 and the nerves. The reason for that is there is less 3 potential to cause pain or bleeding.</p> <p>4 Q. So there's a nerve bundle, sometimes called 5 the obturator nerve bundle, that is near where the 6 TVT-O mesh goes; is that correct?</p> <p>7 A. They're in the same foramen. They're about 8 3 centimeters away from each other.</p> <p>9 Q. And so when placing the TVT-Obturator 10 device, it's important to be aware of this proximity 11 to the nerves so that you don't have complications 12 associated with pain; is that correct?</p> <p>13 A. That's correct.</p> <p>14 Q. And so that you don't have complications 15 associated with nerve damage, correct?</p> <p>16 A. Correct.</p> <p>17 Q. So one of the risks associated with using 18 the TVT-Obturator device is nerve damage and pain 19 associated with nerve damage that can occur if you 20 don't place the mesh correctly?</p> <p>21 A. Yes.</p> <p>22 Q. And those obturator nerves as you -- you 23 actually have a picture on page 21 of your report 24 where you show that 2-and-a-half to 3-centimeter space 25 that is the foramen, correct?</p>

<p style="text-align: right;">Page 50</p> <p>1 A. Yes.</p> <p>2 Q. And you show little branches of nerves</p> <p>3 coming off of that area, correct?</p> <p>4 A. Correct.</p> <p>5 Q. And you know from your training and</p> <p>6 experience that those nerves are differently placed in</p> <p>7 patients, correct?</p> <p>8 A. Incorrect. I find them to be fairly</p> <p>9 consistent, in the same location.</p> <p>10 Q. You do, okay.</p> <p>11 And have you -- when implanting a TVT-O</p> <p>12 device, to your knowledge, have you ever had a patient</p> <p>13 who had nerve pain?</p> <p>14 A. Have I ever had a patient that I implanted</p> <p>15 with nerve pain?</p> <p>16 Q. Yes.</p> <p>17 A. Yes.</p> <p>18 Q. And was that because you didn't properly do</p> <p>19 the procedure, or some other reason?</p> <p>20 A. It's hard to say. I can't be certain it</p> <p>21 was even nerve pain. They had groin pain. And groin</p> <p>22 pain could be a variety of things. But I certainly</p> <p>23 have had patients that have had groin pain after a</p> <p>24 TVT-Obturator or TVT-Abbrevio.</p> <p>25 Q. Have you ever had a patient that you</p>	<p style="text-align: right;">Page 52</p> <p>1 foramen.</p> <p>2 Q. And did you actually participate in that</p> <p>3 study?</p> <p>4 A. I did.</p> <p>5 Q. Was that study ever published?</p> <p>6 A. It was.</p> <p>7 Q. And what were the results of that study?</p> <p>8 A. The results were that the products were</p> <p>9 very similar in terms of their location to the</p> <p>10 obturator nerve bundle. There were some very slight</p> <p>11 differences in the location, but there was no clinical</p> <p>12 correlation. It was just a purely cadaveric anatomic</p> <p>13 radiographic study.</p> <p>14 Q. Did you feel that the techniques that were</p> <p>15 used in that study were valid and reliable techniques?</p> <p>16 A. There were some limitations, but I think,</p> <p>17 for the most part, it was valid.</p> <p>18 Q. Do you cite to that study in the body of</p> <p>19 your report?</p> <p>20 A. I would have to take a look here. Yeah, we</p> <p>21 did cite that. It's a 2011 article, "Anatomic</p> <p>22 comparison" -- no, that's the other. No, I don't see</p> <p>23 it here. There's one study from Peter Hinoul that we</p> <p>24 cited, but I don't believe we cited that article.</p> <p>25 Q. And who was the lead author on that</p>
<p style="text-align: right;">Page 51</p> <p>1 implanted with a TVT-O device that had persistent,</p> <p>2 chronic groin or thigh pain?</p> <p>3 A. I can't think of a patient. Or there may</p> <p>4 be one out there that didn't return to me for</p> <p>5 follow-up, but I'm not immediately aware of anybody.</p> <p>6 Q. You were actually asked to do a study on</p> <p>7 the proximity of the TVT-O mesh to the nerve bundle;</p> <p>8 is that correct?</p> <p>9 A. We did a study comparing the anatomical</p> <p>10 position of TVT-O versus Monarc. I think that may be</p> <p>11 the study you're referring to.</p> <p>12 Q. And can you -- with whom did you do that</p> <p>13 study?</p> <p>14 A. That was a study that was sponsored by</p> <p>15 Ethicon. Myself, Dr. Mark Walters were the two</p> <p>16 physicians that did the cadaveric work on that. There</p> <p>17 was radiology people involved. Dr. Peter Hinoul was</p> <p>18 involved. There were about five or six physicians</p> <p>19 that were in the project.</p> <p>20 Q. And that project was to determine whether</p> <p>21 the TVT-Obturator was -- when implanted properly, was</p> <p>22 closer to the obturator bundle than the Monarc; is</p> <p>23 that correct?</p> <p>24 A. We wished to compare the two, TVT-O versus</p> <p>25 Monarc, and their anatomical position in the obturator</p>	<p style="text-align: right;">Page 53</p> <p>1 article?</p> <p>2 A. Piet Hinoul.</p> <p>3 Q. And where was that published?</p> <p>4 A. I believe the -- I could look on my CV.</p> <p>5 It's on my CV.</p> <p>6 Q. Doctor, I'm going to hand you what's been</p> <p>7 marked previously as Exhibit 5. That's your CV, I</p> <p>8 believe, correct?</p> <p>9 A. Yes, that's correct.</p> <p>10 Q. And can you find that study on your CV,</p> <p>11 please?</p> <p>12 A. So it published in 2013. And the title was</p> <p>13 "A novel radiographic technique to assess implant</p> <p>14 grafts in the female pelvis: a comparison of the</p> <p>15 Inside-Out and Outside-in transobturator and</p> <p>16 midurethral sling positioning." And it's published in</p> <p>17 Obstetrics and Gynecology Journal, 2013.</p> <p>18 Q. Doctor, I'm wondering why that paper isn't</p> <p>19 cited in your report.</p> <p>20 A. I didn't feel there was anything real</p> <p>21 significant that came out of that study, so it wasn't</p> <p>22 something that I needed to rely on in basing my</p> <p>23 opinions.</p> <p>24 Q. And it's also not on your reliance</p> <p>25 materials; is that correct?</p>

<p style="text-align: right;">Page 54</p> <p>1 A. That's correct.</p> <p>2 Q. Do you recall, Dr. Flynn, what the</p> <p>3 conclusions of that study that you did were with</p> <p>4 regard to -- strike that.</p> <p>5 The study, Doctor, that's not referenced in</p> <p>6 your report and not on your reliance materials that</p> <p>7 you did with Ethicon with Dr. Hinoul was comparing the</p> <p>8 distance from the obturator nerve bundle when using a</p> <p>9 TVT-Obturator as compared to the AMS Obturator device,</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 Q. And do you recall what the conclusion was</p> <p>13 that was reached in that study about the distance of</p> <p>14 those two devices from the obturator bundle?</p> <p>15 A. I would have to look at the study again. I</p> <p>16 don't recall the conclusion.</p> <p>17 Q. It was -- distance from the obturator</p> <p>18 bundle is important enough to do a study on, correct?</p> <p>19 A. Correct.</p> <p>20 Q. Because if the TVT-Obturator actually came</p> <p>21 closer to the obturator bundle, it could increase the</p> <p>22 risk of nerve pain and nerve damage when using the</p> <p>23 TVT-Obturator as compared to the AMS device, correct?</p> <p>24 A. Correct.</p> <p>25 Q. And if studies demonstrated that the</p>	<p style="text-align: right;">Page 56</p> <p>1 In that sentence, Doctor, you're comparing</p> <p>2 Dr. de Leval's inside-out technique to Dr. Delorme's</p> <p>3 outside-in technique, correct?</p> <p>4 A. There's a lot in that paragraph. It's just</p> <p>5 generally describing why it was created and what the</p> <p>6 goals of it were.</p> <p>7 Q. And one of the goals that you opine about</p> <p>8 is that the inside-out approach, as used with the</p> <p>9 TVT-O -- one of the benefits of that approach was that</p> <p>10 you would be further from the obturator nerves and</p> <p>11 obturator bundle, correct?</p> <p>12 A. Correct.</p> <p>13 Q. As compared to the AMS device, correct?</p> <p>14 A. Any device in general. There's a number of</p> <p>15 outside-to-in devices.</p> <p>16 Q. Okay. As compared to any outside-in</p> <p>17 device, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And you say that one of the benefits for</p> <p>20 patients of being further from the obturator bundle is</p> <p>21 reducing potential complications from stress urinary</p> <p>22 incontinence surgery, correct?</p> <p>23 A. Correct.</p> <p>24 Q. So you would agree, Doctor, that if the</p> <p>25 TVT-Obturator consistently was demonstrated to be</p>
<p style="text-align: right;">Page 55</p> <p>1 TVT-Obturator consistently came closer to the</p> <p>2 obturator nerve bundle than the AMS Obturator device,</p> <p>3 that's something that you as a treating physician</p> <p>4 would want to know, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And that's something that, as a treating</p> <p>7 physician, might inform your decision whether to use</p> <p>8 the TVT-Obturator or the AMS device, correct?</p> <p>9 A. Correct.</p> <p>10 Q. So if you turn to page 21 of your report,</p> <p>11 Doctor, you say -- have you got that?</p> <p>12 A. Yes.</p> <p>13 Q. You say in the first paragraph, about</p> <p>14 midway through, "The unique inside-to-out approach</p> <p>15 created by Dr. de Leval to allow a greater distance</p> <p>16 between the implanted mesh and the obturator nerve,</p> <p>17 thereby reducing potential complications in SUI</p> <p>18 surgery"; is that what you wrote?</p> <p>19 A. Yes.</p> <p>20 Q. And what you mean there is that</p> <p>21 Dr. de Leval's inside-out procedure as compared to</p> <p>22 Dr. Delorme's outside-in procedure, as used with the</p> <p>23 AMS product, it was your expert opinion that the</p> <p>24 inside-out -- one of the benefits -- that was messy,</p> <p>25 so let me start that over.</p>	<p style="text-align: right;">Page 57</p> <p>1 closer to the obturator nerve bundle than an</p> <p>2 outside-in mesh, that there would be more risk with</p> <p>3 the TVT-O of nerve damage, correct?</p> <p>4 A. Incorrect. Not necessarily.</p> <p>5 Q. If the TVT-Obturator were closer to the</p> <p>6 nerves consistently than an outside-in device,</p> <p>7 wouldn't that increase the likelihood or the risk of</p> <p>8 having nerve damage?</p> <p>9 A. The distance would have to be a significant</p> <p>10 distance, and it would have to be statistically</p> <p>11 significant as well as clinically significant. If</p> <p>12 we're talking about a few millimeters, I don't think</p> <p>13 that's clinically significant. I don't think it's</p> <p>14 statistically significant.</p> <p>15 Q. I notice that, when you wrote this</p> <p>16 sentence, you didn't cite to any science to support</p> <p>17 your expert opinion. Why is that?</p> <p>18 A. Because these are theoretical goals, you</p> <p>19 know, that were proposed by Dr. de Leval, so this is</p> <p>20 Dr. de Leval's thoughts and why he created the device.</p> <p>21 Later in the report I do cite information on the</p> <p>22 incidence of groin pain. I do that in great detail</p> <p>23 later on. And we discuss the systematic reviews and</p> <p>24 the RCTs and the meta-analyses with respect to the TVT</p> <p>25 and TVT-O product.</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. So is it fair to say, then, that this</p> <p>2 statement that the inside-to-out approach allows a</p> <p>3 greater distance between the mesh and the obturator</p> <p>4 nerve, thereby reducing potential complications, is it</p> <p>5 fair to say that that is not your expert opinion?</p> <p>6 A. It's my expert opinion that that's why</p> <p>7 Dr. de Leval created the device. He wanted to allow a</p> <p>8 greater distance between the mesh and the obturator</p> <p>9 nerve. That's what that statement says.</p> <p>10 Q. And what is your expert opinion, if you</p> <p>11 have any, on whether or not that is a benefit that was</p> <p>12 realized with the TVT-O?</p> <p>13 In other words, is it your expert opinion</p> <p>14 that the TVT-O does, in fact, allow the mesh to lie</p> <p>15 further from the obturator nerve than does an</p> <p>16 outside-in mesh?</p> <p>17 A. It's very controversial, so you'll have</p> <p>18 some reports that say the outside-to-in is superior</p> <p>19 and others who say the inside-to-out is superior.</p> <p>20 Q. And I notice, Doctor, that you do not cite</p> <p>21 in your expert report or in your reliance materials</p> <p>22 the Zahn study, Z-a-h-n, which I'll hand to you as</p> <p>23 Exhibit 13.</p> <p>24 (Exhibit 13 was marked for identification.)</p> <p>25 MR. KOOPMANN: A copy for me, Counsel?</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. And the difference is not a function of a</p> <p>2 few millimeters, it's actually 1 centimeter</p> <p>3 difference, correct?</p> <p>4 A. Correct.</p> <p>5 Q. So this study demonstrates that the</p> <p>6 TVT-Obturator is statistically significantly closer to</p> <p>7 the obturator nerve and bundle than is the Monarc,</p> <p>8 correct?</p> <p>9 A. According to this study.</p> <p>10 Q. And that distance of 1 centimeter closer to</p> <p>11 the obturator nerve bundle, that is a significant</p> <p>12 difference, correct, clinically?</p> <p>13 A. Clinically, 1 centimeter is a big distance,</p> <p>14 yes, in surgery.</p> <p>15 Q. And I notice also that you did not cite to,</p> <p>16 in your report or your reliance materials, the Achtari</p> <p>17 study, A-c-h-t-a-r-i; is that correct?</p> <p>18 A. That is correct.</p> <p>19 (Exhibit 14 was marked for identification.)</p> <p>20 Q. And I'm handing you Exhibit 14, Doctor,</p> <p>21 which is the Achtari study. And see in the</p> <p>22 conclusions in the abstract, it says, "The in-out</p> <p>23 technique" -- that would be the TVT-Obturator,</p> <p>24 correct?</p> <p>25 A. Correct.</p>
<p style="text-align: right;">Page 59</p> <p>1 MR. ZONIES: I do.</p> <p>2 MR. KOOPMANN: Thank you.</p> <p>3 Q. (By Mr. Zonies) Have you ever seen that</p> <p>4 study before, Doctor?</p> <p>5 A. No, I don't believe so.</p> <p>6 Q. And the Zahn study, Doctor, if you look at</p> <p>7 the conclusion, it says, "The outside-in technique</p> <p>8 results in the mesh being placed farther from the</p> <p>9 obturator canal and closer to the ischiopubic ramus,</p> <p>10 theoretically reducing the risk of neurovascular</p> <p>11 injury." Is that what that says?</p> <p>12 A. That's what that says.</p> <p>13 Q. And if you look on the third page of the</p> <p>14 study, page 703 of the journal American College of</p> <p>15 Obstetricians and Gynecologists, there's a Table 1.</p> <p>16 Do you see Table 1?</p> <p>17 A. Yes.</p> <p>18 Q. And Table 1 describes the distance between</p> <p>19 the transobturator tapes and the obturator canal</p> <p>20 according to left- and right-side placement, correct?</p> <p>21 A. Correct.</p> <p>22 Q. And in Table 1, you can see that there is a</p> <p>23 statistically significant difference between the TVT-O</p> <p>24 and the outside-in approach, correct?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. "The in-out technique is the closest to the</p> <p>2 obturator canal," correct?</p> <p>3 A. Where are you reading from?</p> <p>4 Q. The abstract conclusion, last sentence,</p> <p>5 "The in-out technique is the closest to the obturator</p> <p>6 canal." That's what that says, correct?</p> <p>7 A. That's what that statement says.</p> <p>8 Q. And lastly, Doctor, in your report, you do</p> <p>9 not cite to the Spinoso study, S-p-i-n-o-s-a; is that</p> <p>10 correct?</p> <p>11 A. That's correct.</p> <p>12 Q. And it's also not in your reliance</p> <p>13 materials, Doctor. Although, I will say that I</p> <p>14 believe that the study is on one of the thumb drives</p> <p>15 you gave me this morning, okay?</p> <p>16 A. Maybe.</p> <p>17 (Exhibit 15 was marked for identification.)</p> <p>18 Q. And so I'm handing you Exhibit 15, Doctor,</p> <p>19 which is the Spinoso study. And if you look at the</p> <p>20 "Results" section on the front page, it says, "With</p> <p>21 the inside-out technique" -- that's the TVT-Obturator,</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. "...the safety margins were reduced and the</p> <p>25 external pudendal vessels and the posterior branch of</p>

<p style="text-align: right;">Page 62</p> <p>1 the obturator nerve were at greater risk of injury,"</p> <p>2 is that what that says?</p> <p>3 A. That's what that says.</p> <p>4 Q. This is important information, Doctor, when</p> <p>5 a physician is trying to make a determination whether</p> <p>6 to use the TVT-Obturator or the Monarc, correct?</p> <p>7 A. Correct.</p> <p>8 Q. In fact, the conclusion in Spinosa says,</p> <p>9 "The two techniques," meaning outside-in versus</p> <p>10 inside-out, "are not equivalent with a lower risk of</p> <p>11 injury to vascular and nerve structures with the</p> <p>12 outside-in technique." That's what it says in the</p> <p>13 conclusion, correct?</p> <p>14 A. Correct.</p> <p>15 Q. And you would agree with that if, indeed,</p> <p>16 these studies demonstrated, as they say, that the</p> <p>17 outside-in technique is -- lays the mesh further from</p> <p>18 the obturator bundle, correct?</p> <p>19 A. That's the conclusion of these three</p> <p>20 studies that you've shown me. That's not my own</p> <p>21 personal experience with the device. That's not what</p> <p>22 any of the systematic reviews or RCTs show.</p> <p>23 Q. But that is certainly what these three</p> <p>24 studies that aren't cited in your report, are not in</p> <p>25 your reliance materials -- that is what these three</p>	<p style="text-align: right;">Page 64</p> <p>1 hips in flexion. So I don't know if this is even</p> <p>2 necessarily representative of what happens clinically</p> <p>3 when you place a mesh on a cadaver that's lying</p> <p>4 supine.</p> <p>5 Q. But certainly, when you studied the issue,</p> <p>6 you chose to use cadavers, and that was a reliable and</p> <p>7 scientific method, correct?</p> <p>8 A. Can you repeat the question?</p> <p>9 Q. Sure. When you chose to study whether the</p> <p>10 inside-out or outside-in technique placed the mesh</p> <p>11 closer to the obturator bundle, you studied that using</p> <p>12 cadavers, correct?</p> <p>13 A. Correct.</p> <p>14 Q. Because that is a reliable and scientific</p> <p>15 way to study that issue, correct?</p> <p>16 A. Incorrect.</p> <p>17 Q. You don't think that that's a reliable way</p> <p>18 to study the issue?</p> <p>19 A. It's not as reliable as human studies, live</p> <p>20 studies, meta-analyses, systematic reviews. It's one</p> <p>21 way of studying the problem, but there's a lot of</p> <p>22 limitations in the cadaveric studies.</p> <p>23 Q. But Doctor, you would agree that if the</p> <p>24 inside-out technique placed the mesh 1 centimeter</p> <p>25 closer to the obturator nerve bundle, on average, that</p>
<p style="text-align: right;">Page 63</p> <p>1 studies demonstrate, correct?</p> <p>2 MR. KOOPMANN: Object to the form.</p> <p>3 A. These are three studies that show that the</p> <p>4 outside-to-in has a greater distance than inside-out.</p> <p>5 That's what these three studies show.</p> <p>6 Q. (By Mr. Zonies) And the three studies show</p> <p>7 that because of that difference, statistically</p> <p>8 significant difference, there is likely a smaller risk</p> <p>9 of nerve injury and pain associated with the</p> <p>10 outside-in technique as compared to the inside-out</p> <p>11 technique, correct?</p> <p>12 A. That's not correct.</p> <p>13 Q. Doctor, if it were true, as these studies</p> <p>14 state, that the inside-out technique places the mesh</p> <p>15 closer to the obturator bundle and, as you've said,</p> <p>16 significantly closer to the obturator bundle, than the</p> <p>17 outside-in technique, as a treating physician, isn't</p> <p>18 that something that you would want to know?</p> <p>19 A. It's one of many factors I want to know.</p> <p>20 These are cadaveric studies. I'm going to rely more</p> <p>21 on my experience, more on clinical studies,</p> <p>22 meta-analyses, much higher levels of evidence than</p> <p>23 these studies that have no more than seven, eight</p> <p>24 cadavers in each study. There's limitations when</p> <p>25 you're placing mesh on cadavers. You can't place the</p>	<p style="text-align: right;">Page 65</p> <p>1 that you increase the risk of nerve damage, correct?</p> <p>2 A. Correct.</p> <p>3 Q. Doctor, I'm going to hand you what I'm</p> <p>4 marking as Exhibit 16.</p> <p>5 (Exhibit 16 was marked for identification.)</p> <p>6 Q. Have you seen that document before?</p> <p>7 A. Yes.</p> <p>8 Q. What is Exhibit 16?</p> <p>9 A. This is a news article that we had</p> <p>10 published in Urology Times, which is a magazine for</p> <p>11 urologists, that talks about the various midurethral</p> <p>12 slings products.</p> <p>13 Q. And so this is an article that you are a</p> <p>14 co-author on, correct?</p> <p>15 A. Correct.</p> <p>16 Q. What was your role in writing this article?</p> <p>17 A. I was asked by Urology Times to write an</p> <p>18 article comparing and contrasting the various</p> <p>19 midurethral slings that were on the market.</p> <p>20 Q. And did you actually write this piece?</p> <p>21 A. Yes, myself and my fellow doctor,</p> <p>22 Nikolavsky.</p> <p>23 Q. Nikolavsky, N-i-k-o-l-a-v-s-k-y.</p> <p>24 That's a physician that you work with?</p> <p>25 A. A physician I trained. He's no longer with</p>

<p style="text-align: right;">Page 66</p> <p>1 me, but he was my fellow at the time we wrote this 2 article 2010 to 2011.</p> <p>3 Q. Would you consider yourself the lead author 4 of this article?</p> <p>5 A. Senior author.</p> <p>6 Q. And so question number one, Doctor, is, I 7 did not see this article cited in your report or on 8 your reliance materials.</p> <p>9 A. Correct.</p> <p>10 Q. I also didn't see it on your CV. Is that 11 correct?</p> <p>12 A. Correct.</p> <p>13 Q. Is there a reason you chose not to disclose 14 this article on your CV or in your report?</p> <p>15 A. Yes.</p> <p>16 Q. What is that reason?</p> <p>17 A. Because this is very low evidence. The CV 18 is prepared primarily for academic rank, and the 19 articles need to be peer reviewed. This is not a 20 peer-reviewed article. This is a newspaper article, 21 essentially. So this is the lowest evidence possible.</p> <p>22 So there's a lot of media and publications, 23 interviews and things that we produce that don't 24 appear on our CV because they're low evidence. 25 They're not peer reviewed. So the school, the</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. This isn't something you would want to 2 present in a courtroom to a judge or a jury?</p> <p>3 A. No.</p> <p>4 Q. Why not?</p> <p>5 A. Because it's not as academically rigorous 6 as other documents that I rely on.</p> <p>7 Q. On the second page, page 29 of Exhibit 16, 8 Doctor, if you turn to that, the last full paragraph 9 starts with "The primary drawback." Do you see that 10 paragraph?</p> <p>11 A. What page?</p> <p>12 Q. The second page. It's page 29 on the top. 13 You have a section entitled "Transobturator tapes"; is 14 that right?</p> <p>15 A. Yes.</p> <p>16 Q. And the last full paragraph in that column 17 starts with, "The primary drawback"; do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And you write there, "The primary drawback 20 of TOT." What do you mean when you say "TOT"?</p> <p>21 A. Those would be a group of slings that 22 traverse the obturator frame in both inside-to-out and 23 outside-to-in, so all of the products.</p> <p>24 Q. So there, you would be including the TVT-O, 25 correct?</p>
<p style="text-align: right;">Page 67</p> <p>1 recommendations for the promotion committee is that we 2 don't list these.</p> <p>3 Q. And would it be your -- what do you mean by 4 "low evidence"?</p> <p>5 A. This is an informal review of the 6 literature. There's no statistics in here. There's 7 no scientific method. So this would be at the level 8 of a book chapter or something of that variety. It 9 doesn't go through the peer-review process.</p> <p>10 Q. Well, you do have opinions in here, 11 correct, about the various devices?</p> <p>12 A. Yeah, there's quite a bit of information we 13 provide in the article.</p> <p>14 Q. Do you believe this to be reliable 15 scientific information?</p> <p>16 A. At least at the time when I wrote that. I 17 wrote this in 2010, so these are my thoughts in 2010. 18 My thoughts may have changed or evolved since then 19 based on new publications and meta-analyses and things 20 that have become available.</p> <p>21 Q. And when you say this is very low evidence, 22 what do you mean by that?</p> <p>23 A. There's a pyramid of evidence that is 24 widely recognized in medicine, and these sort of -- 25 this type of article is on the bottom.</p>	<p style="text-align: right;">Page 69</p> <p>1 A. Correct.</p> <p>2 Q. And so you write, the primary drawback of 3 the TVT-O and other transobturator slings is an 4 increased incidence of groin pain and vaginal wall 5 extrusion. That's what you wrote, correct?</p> <p>6 A. That's one of many things I wrote in that 7 paragraph.</p> <p>8 Q. And is that still your expert opinion 9 today?</p> <p>10 A. Yes.</p> <p>11 Q. You also wrote that "The TOT," which 12 includes the TVT-O, "is often palpable deep to the 13 vaginal wall as it interacts with a longer segment of 14 the vaginal wall than the classic TVT and therefore is 15 more likely to result in vaginal wall exposure or 16 dyspareunia." Is that also your expert opinion today?</p> <p>17 A. Where are you reading? In the same 18 paragraph?</p> <p>19 Q. Sure. Yeah, the next sentence in that 20 paragraph. So if you're with me, Doctor, the next 21 sentence in the paragraph is, "The TOT," which 22 includes the TVT-O, correct?</p> <p>23 A. Correct.</p> <p>24 Q. "...is often palpable deep to the vaginal 25 wall, as it interacts with a longer segment (4 to 6</p>

<p style="text-align: right;">Page 70</p> <p>1 centimeters) of the vaginal wall than classic TVT and 2 therefore is more likely to result in vaginal wall 3 exposure or dyspareunia." That's what you wrote in 4 2010, correct? 5 A. Correct. 6 Q. Is that still your expert opinion today? 7 A. Yes. 8 Q. And then if you look, Doctor, on the last 9 page of your article published in 2010, you write in 10 the -- very near the end of this bottom middle column, 11 a sentence starts with, "However"; do you see that? 12 A. Yes. 13 Q. "However, the trade-off is a small but 14 significant incidence of groin pain, vaginal wall 15 extrusion, and inferior efficacy in patients with 16 ISD." And there you're comparing the TVT-O to the 17 TVT; is that correct? 18 A. I'm comparing retropubic tapes to 19 transobturator tapes as a group. 20 Q. And the group of transobturator tapes would 21 include the TVT-O, correct? 22 A. Correct. 23 Q. And so in this statement, you're saying the 24 trade-off for using a TVT-Obturator as compared to a 25 retropubic device is a small but significant incidence</p>	<p style="text-align: right;">Page 72</p> <p>1 opinions. This is not a systematic review. It's not 2 a meta-analysis. 3 Q. I noticed in your report, Doctor, those two 4 sections we just read that discuss the potential 5 problems associated with using a transobturator device 6 such as the TVT-O, those aren't referred to in any way 7 in your report, correct? 8 A. I believe I do bring that up in my report. 9 Later in the report there's more information that we 10 discuss in regards to the TVT-Obturator product. 11 Q. You would consider, as you said, Doctor, 12 that your -- what's reflected in Exhibit 16, the 13 article that you wrote and published in Urology Times 14 "very low evidence," correct? 15 A. Yes. 16 Q. Doctor, could you turn to page 24 of your 17 report, please. Have you got that? 18 A. I do. 19 Q. And you testified, Doctor, that in drafting 20 your report, you did not refer to or review 21 Exhibit 16, the article we're looking at, correct? 22 A. Correct. 23 Q. There's a paragraph in the middle of page 24 24 that starts with, "There is currently 3-year data"; 25 do you see that?</p>
<p style="text-align: right;">Page 71</p> <p>1 of groin pain, vaginal wall extrusion, and inferior 2 efficacy in patients with ISD when using the TVT-O 3 device, correct? 4 A. Correct. 5 Q. Is that still your expert opinion today? 6 A. That's my opinion, yes. 7 Q. Were you aware of this article, Doctor, 8 when you were writing your expert report in this case? 9 A. I was. 10 Q. Did you refer to this article at all when 11 writing your expert report in this case? 12 A. I did not. 13 Q. Did you -- was there a reason you didn't 14 refer to this when writing your expert report? 15 A. Yes. 16 Q. What was the reason? 17 A. Because this is low evidence, as I've 18 mentioned earlier. It's essentially a newspaper 19 article. I relied on systematic reviews, 20 meta-analyses, and prospective randomized studies. 21 For the most part, I relied on the original 22 references, so instead of citing this article, this 23 article just cites a bunch of other references, so I 24 tried to go back to the original source. There's 25 nothing original, really, in this article beyond my</p>	<p style="text-align: right;">Page 73</p> <p>1 A. Yes. 2 Q. I'm going to read that, and I want you to 3 correct me if I get anything wrong. 4 "There are currently 3-year data and 9 RCTs 5 on Classic TVT-O that demonstrate long-term success in 6 as many as 95% of patients," did I read that 7 correctly? 8 A. Yes. 9 Q. Doctor, I was reading from Exhibit 16, the 10 article that you wrote in 2010. You copied that for 11 your expert report, didn't you, word for word? 12 A. I don't know. This is -- like I mentioned 13 earlier, about 50 percent of this report appears in my 14 TVT report, so these are my opinions, my thoughts, so 15 this is -- that's my statement. I used it in two 16 different articles. 17 Q. Well, you know, Doctor, as of today, as of 18 the date you wrote your report, there are more than 19 nine RCTs on TVT-O, correct? 20 A. I would have to go back and count, but I 21 know there's at least nine RCTs on TVT-O. 22 Q. So let's back up and go to page 22 of your 23 report, Doctor. The paragraph just above Section C, 24 starts with "Transobturator tapes"; do you see that? 25 A. Yes.</p>

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<p>1 Q. I'm going to read from Exhibit 16, Doctor,</p> <p>2 the article you published in 2010. I want you to</p> <p>3 follow along in your report, and I want you to tell me</p> <p>4 if I missed anything, okay?</p> <p>5 "Transobturator tapes are tunnelled through</p> <p>6 the obturator foramen. They were introduced to</p> <p>7 further reduce morbidity and convalescence of MUS</p> <p>8 surgery by avoiding the retropubic space," did I read</p> <p>9 that correctly?</p> <p>10 A. I can see where you're -- on page 22. I</p> <p>11 don't see where you're looking at on Exhibit 16.</p> <p>12 Q. So if you look on Exhibit 16, right where</p> <p>13 it says "Transobturator tapes."</p> <p>14 A. Okay.</p> <p>15 Q. That's copied word for word from what you</p> <p>16 wrote in 2010, right?</p> <p>17 A. The first sentence on Exhibit 16?</p> <p>18 Q. Yes. In fact, the second sentence, and the</p> <p>19 third sentence, and the fourth -- in fact, that whole</p> <p>20 paragraph is copied word for word from what you wrote</p> <p>21 in 2010, correct, Doctor?</p> <p>22 A. I have to look at this more closely.</p> <p>23 There's a lot here that you're asking me to read, two</p> <p>24 paragraphs and compare the two paragraphs.</p> <p>25 Q. Well, Doctor, I'll read from Exhibit 16,</p>	<p>1 A. No, that's not true.</p> <p>2 Q. You testified, Doctor, that you didn't even</p> <p>3 refer to Exhibit 16 when writing your report, correct?</p> <p>4 A. Correct.</p> <p>5 Q. Is that true as you're sitting here today?</p> <p>6 That's your belief?</p> <p>7 A. Exhibit 16 is not cited in my report.</p> <p>8 Q. But you testified you didn't even refer to</p> <p>9 it, correct?</p> <p>10 A. I don't know what you mean by "refer to</p> <p>11 it."</p> <p>12 Q. You didn't even look at it when preparing</p> <p>13 your report, correct?</p> <p>14 A. I mean, I have knowledge of this, I wrote</p> <p>15 it, so it's something that I recall. I don't know if</p> <p>16 I read it immediately before preparing this report,</p> <p>17 but certainly I have knowledge of this article.</p> <p>18 Q. So Doctor, I'm going to read -- do you see</p> <p>19 the next sentence that starts with "The vaginal</p> <p>20 dissection" in your report, same paragraph?</p> <p>21 A. Yes.</p> <p>22 Q. I'll read from Exhibit 16, if you follow</p> <p>23 along in your report. And you can stop me if there's</p> <p>24 a difference.</p> <p>25 "The vaginal dissection is similar to TVT</p>
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<p>1 and you can follow along in your expert report, okay?</p> <p>2 A. Okay.</p> <p>3 Q. "Transobturator tapes are tunnelled through</p> <p>4 the obturator foramen," is that the same?</p> <p>5 A. And which paragraph are you looking at</p> <p>6 here?</p> <p>7 Q. Page 22, the one that starts with</p> <p>8 "Transobturator tapes," do you see that?</p> <p>9 A. It says, "Transobturator tapes are</p> <p>10 tunnelled through the obturator foramen and were</p> <p>11 introduced to further reduce morbidity and</p> <p>12 convalescence."</p> <p>13 Q. "...of MUS surgery by avoiding the</p> <p>14 retropubic space." That's the same, right, word for</p> <p>15 word?</p> <p>16 A. No.</p> <p>17 MR. KOOPMANN: Object to form.</p> <p>18 A. It's not the same.</p> <p>19 Q. (By Mr. Zonies) So Doctor, my question to</p> <p>20 you is, did you write that paragraph on page 22 in</p> <p>21 your report?</p> <p>22 A. I did.</p> <p>23 Q. When you wrote that in your report on page</p> <p>24 22, isn't it true you copied and pasted what you wrote</p> <p>25 in 2010?</p>	<p>1 with the exception of the angle of dissection which is</p> <p>2 at a 45-degree angle to the ischiopubic ramus."</p> <p>3 That's exactly what it says in your report, correct?</p> <p>4 A. Correct.</p> <p>5 Q. Your report then says -- Exhibit 16 says,</p> <p>6 "TOT," which you replaced in your report with</p> <p>7 TVT-Obturator, "TOT tunnel does not traverse the</p> <p>8 retropubic space which may be scarred from prior</p> <p>9 operations and eliminates the potential for bowel</p> <p>10 injury." That's word for word what's in your report,</p> <p>11 correct?</p> <p>12 A. Correct.</p> <p>13 Q. Next sentence, "Many gynecologic surgeons,"</p> <p>14 you added "urologic," correct?</p> <p>15 A. "Many urologic and gynecologic surgeons."</p> <p>16 Q. "...prefer the transobturator route as they</p> <p>17 are fearful of causing a bladder injury that more</p> <p>18 commonly occurs with retropubic trocar passage."</p> <p>19 That's what is in your report and in what you</p> <p>20 published in 2010, correct?</p> <p>21 A. Correct.</p> <p>22 Q. Is it your testimony as you're sitting here</p> <p>23 today, Doctor, that in January of 2016, you wrote the</p> <p>24 words in your report that are almost identical to the</p> <p>25 words you wrote six years earlier in this article</p>

<p style="text-align: right;">Page 78</p> <p>1 without referencing the article?</p> <p>2 A. These statements that I have in this</p> <p>3 report, many of these are statements that I've used</p> <p>4 many, many times over and over again. I've been very</p> <p>5 consistent in my opinions. So these are key opinions</p> <p>6 that I keep and maintain. I've used them in many</p> <p>7 reports. As I mentioned earlier, much of this report</p> <p>8 has come from a previous report. I've used it in</p> <p>9 publications. I've used it in PowerPoints. I've used</p> <p>10 it when speaking publically and making presentations at</p> <p>11 scientific meetings. These are statements that I've</p> <p>12 used when I teach my residents and fellows. So these</p> <p>13 are statements that I rely on. These are statements</p> <p>14 that I have confidence in. These are statements that</p> <p>15 I often repeat, yes. I do repeat these statements.</p> <p>16 Q. So what I just read from your expert report</p> <p>17 was indeed copied from some other source and put into</p> <p>18 your expert report, correct?</p> <p>19 A. That's not correct.</p> <p>20 Q. It's your testimony that you typed those</p> <p>21 words totally new without referring to your article in</p> <p>22 2010, or any other source?</p> <p>23 A. As I mentioned earlier, these are</p> <p>24 statements that I've repeated many times. And so I</p> <p>25 continue to repeat them. I've used them in other</p>	<p style="text-align: right;">Page 80</p> <p>1 the risk of injury to bladder, bowel, and vascular</p> <p>2 structures and has less post-operative voiding</p> <p>3 dysfunction."</p> <p>4 Is that what you wrote in both 2010 and also</p> <p>5 in 2016 in your expert report?</p> <p>6 A. Correct.</p> <p>7 Q. Is it your testimony, Doctor, that when</p> <p>8 writing your expert report, those words came out for</p> <p>9 the first time in that order saying that thing, or did</p> <p>10 you copy and paste that from some other source?</p> <p>11 MR. KOOPMANN: Object to form.</p> <p>12 A. Neither. I don't agree with either of</p> <p>13 those statements. Like I said earlier, these are</p> <p>14 statements that I commonly repeat. I've used them</p> <p>15 many times. I stand behind them. I've used them in</p> <p>16 other reports, as we mentioned earlier. You know, 70,</p> <p>17 80 percent of this report has come from a previous</p> <p>18 report. So these are statements that I've repeated,</p> <p>19 statements that I have not changed my opinions on.</p> <p>20 These are my opinions.</p> <p>21 Q. (By Mr. Zonies) This sentence about the</p> <p>22 transobturator approach, did this come from some other</p> <p>23 report?</p> <p>24 A. It may have. It may not have. These</p> <p>25 are -- I repeat things often. And these are</p>
<p style="text-align: right;">Page 79</p> <p>1 reports, publications, presentations.</p> <p>2 Q. If you turn to page 19 of your report,</p> <p>3 Doctor, do you have that? Are you there?</p> <p>4 A. Yes.</p> <p>5 Q. If you look at the first full paragraph,</p> <p>6 last sentence, it begins with the words, "The</p> <p>7 transobturator approach"; do you see that?</p> <p>8 A. The last paragraph of the --</p> <p>9 Q. The last sentence of the first full</p> <p>10 paragraph.</p> <p>11 A. The first full paragraph?</p> <p>12 Q. Yes.</p> <p>13 A. Yes.</p> <p>14 Q. It begins with the words "The</p> <p>15 transobturator approach"; do you see that?</p> <p>16 A. I do.</p> <p>17 Q. If you turn to page 16, Doctor, on the last</p> <p>18 page in the "Conclusions" section, there's also a</p> <p>19 sentence that begins with, "The transobturator</p> <p>20 approach"; do you see that? Right here.</p> <p>21 A. Okay.</p> <p>22 Q. And you can follow in either your report or</p> <p>23 Exhibit 16, Doctor, because they're the same. It</p> <p>24 says, "The transobturator approach enables the surgeon</p> <p>25 to avoid the retropubic space and thereby decreases</p>	<p style="text-align: right;">Page 81</p> <p>1 statements that I've repeated many times. If it</p> <p>2 appears in another report or another publication or</p> <p>3 presentation of mine, I wouldn't be surprised, because</p> <p>4 I tend to say the same thing consistently about these</p> <p>5 products.</p> <p>6 Q. Well, here's my question, Doctor. If you</p> <p>7 look at Exhibit 16, you see the sentence we just read,</p> <p>8 "The transobturator approach enables the surgeon to</p> <p>9 avoid the retropubic space and thereby decreases the</p> <p>10 risk of injury to bladder, bowel, and vascular</p> <p>11 structures and has less post-operative voiding</p> <p>12 dysfunction," right?</p> <p>13 A. Yes.</p> <p>14 Q. That's what you feel is a benefit of the</p> <p>15 TVT-O, correct?</p> <p>16 A. It's one of the many benefits.</p> <p>17 Q. Now, you wouldn't want to hide the</p> <p>18 negatives in writing your expert report, would you?</p> <p>19 A. I try to make my reports as comprehensive</p> <p>20 and informative as possible. The report is prepared</p> <p>21 in order to reflect opinions that I'm going to have in</p> <p>22 this trial and testimony.</p> <p>23 Q. I'd like you to look back at Exhibit 16.</p> <p>24 What is the sentence after the one that's in your</p> <p>25 report that we were just reading in Exhibit 16? What</p>

<p style="text-align: right;">Page 82</p> <p>1 does that sentence say? Could you read that, please?</p> <p>2 A. "However, the trade-off is a small but</p> <p>3 significant incidence of groin pain, vaginal</p> <p>4 extrusion, and inferior efficacy in patients with</p> <p>5 ISD."</p> <p>6 Q. Why did you choose not to include that</p> <p>7 sentence in your expert report, Doctor?</p> <p>8 A. I did include that statement. That's in</p> <p>9 other paragraphs. You got to read the report more</p> <p>10 comprehensively. I pointed that out in other</p> <p>11 sections. And we can go to those sections, if you'd</p> <p>12 like, but I've mentioned in the report that there are</p> <p>13 studies to show that the obturator approach has</p> <p>14 inferior incontinence results in patients with ISDs</p> <p>15 when compared to TVT-O. And I point out in the</p> <p>16 meta-analyses in the Cochrane reviews the advantages</p> <p>17 and disadvantages of the various products. So you're</p> <p>18 just pulling one paragraph out of context. If you</p> <p>19 read the entire 53-page document, we can go to other</p> <p>20 areas in that document that talk about the limitations</p> <p>21 of the product.</p> <p>22 Q. So Doctor, I'm reading on page 19 a</p> <p>23 sentence that mirrors the sentence in the publication</p> <p>24 that you did in 2010. It's word for word the same,</p> <p>25 correct?</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. Now, you wrote that in 2010, correct?</p> <p>2 A. Correct.</p> <p>3 Q. And has there been a single RCT published</p> <p>4 between 2010 and today, or the date that you wrote</p> <p>5 your report, on classic TVT-O?</p> <p>6 A. I'll have to look at the dates of the RCTs</p> <p>7 I quoted. There may have been.</p> <p>8 Q. So when you wrote in your expert report</p> <p>9 "There is currently 3-year data and 9 RCTs on classic</p> <p>10 TVT-O," was that correct or incorrect as of</p> <p>11 February of 2016?</p> <p>12 A. I'd have to go back and look and count. I</p> <p>13 know that there's at least nine RCTs. If there's ten,</p> <p>14 eleven, there could be more. I think the more, the</p> <p>15 better, but definitely I know there's at least nine of</p> <p>16 them.</p> <p>17 Q. And that's because you copied this from</p> <p>18 your 2010 article, or somewhere else, right? That's</p> <p>19 why it says "9 RCTs." You copied it.</p> <p>20 MR. KOOPMANN: Object to form.</p> <p>21 A. I disagree, like I disagreed earlier.</p> <p>22 Q. (By Mr. Zonies) Would you believe me,</p> <p>23 Doctor, if I told you there are more than 21 -- more</p> <p>24 than 20 RCTs on TVT-O as of the date of your report?</p> <p>25 Would that be surprising?</p>
<p style="text-align: right;">Page 83</p> <p>1 A. Correct.</p> <p>2 Q. And then in your 2010 publication, you have</p> <p>3 a balance where you talk about the downsides of the</p> <p>4 TVT-O, correct, in the next sentence?</p> <p>5 A. Correct.</p> <p>6 Q. You deleted that sentence in your expert</p> <p>7 report, correct?</p> <p>8 A. Incorrect.</p> <p>9 Q. Turn back to page 24, Doctor, of your</p> <p>10 expert report, the paragraph that begins with, "There</p> <p>11 is currently 3-year data and 9 RCTs on classic TVT-O";</p> <p>12 do you see that paragraph?</p> <p>13 A. Yes.</p> <p>14 Q. Doctor, I'd like you to look at Exhibit 16,</p> <p>15 what you wrote in 2010, and you'll see that, again,</p> <p>16 those first one, two, three, four sentences are word</p> <p>17 for word what you wrote in 2010, correct?</p> <p>18 A. You have to point out where you're talking</p> <p>19 about. I can see this on page 24, but in</p> <p>20 Exhibit 16 -- which paragraph are we on?</p> <p>21 Q. Sure. On Exhibit 16, if you look at the</p> <p>22 second page, the second paragraph under</p> <p>23 "Transobturator tapes," it says, "There are currently</p> <p>24 3-year data and nine RCTs on Classic TVT-O," right?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 85</p> <p>1 A. There's -- it's a compound sentence, so it</p> <p>2 says there's three-year data, nine RCTs, so, you know,</p> <p>3 there might be RCTs that have shorter data. We were</p> <p>4 trying to include, you know, the longest RCTs,</p> <p>5 three-year data or greater.</p> <p>6 Q. Now, Doctor, if you turn -- did you write</p> <p>7 your TVT-S report before or after your TVT-O report?</p> <p>8 A. I'll have to go back and look at the dates</p> <p>9 on the TVT-S.</p> <p>10 Q. So Doctor, please turn in your report to</p> <p>11 page 51. Now, you were careful when writing your</p> <p>12 report, correct?</p> <p>13 A. I do the best I can to be careful with</p> <p>14 these reports, yes.</p> <p>15 Q. You approach this with the scientific rigor</p> <p>16 of presenting high-level evidence, not very low-level</p> <p>17 evidence, correct?</p> <p>18 A. Correct.</p> <p>19 MR. KOOPMANN: Counsel, your two hours are</p> <p>20 up.</p> <p>21 MR. ZONIES: That's all I have today,</p> <p>22 Doctor, unfortunately, because of a time limit, but</p> <p>23 thank you for your time.</p> <p>24 THE WITNESS: All right. Thank you.</p> <p>25 MR. KOOPMANN: Doctor, I'm going to have a</p>

<p style="text-align: right;">Page 86</p> <p>1 few follow-up questions based on Mr. Zonies'</p> <p>2 questions.</p> <p>3 EXAMINATION</p> <p>4 BY MR. KOOPMANN:</p> <p>5 Q. You were asked some questions earlier about</p> <p>6 your preparation of the TVT-O report and when you did</p> <p>7 that in relation to your TVT report, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Your TVT-Retropubic report was not prepared</p> <p>10 from start to finish solely for purposes of this</p> <p>11 litigation -- this federal-court litigation; is that</p> <p>12 correct?</p> <p>13 A. Correct.</p> <p>14 Q. You had originally prepared a</p> <p>15 TVT-Retropubic report for an earlier case that you're</p> <p>16 no longer dealing with in 2016; is that fair to say?</p> <p>17 A. Yes.</p> <p>18 Q. So some of the time that you spent in</p> <p>19 preparing your TVT-Retropubic report may have been</p> <p>20 billed in a separate case; is that fair to say?</p> <p>21 A. Yes, that's fair to say.</p> <p>22 Q. How long after surgery did you typically</p> <p>23 discharge your TVT-O patients?</p> <p>24 A. They were discharged the same day, the</p> <p>25 overwhelming majority of them, unless the surgery was</p>	<p style="text-align: right;">Page 88</p> <p>1 TVT-Obturator is a good product to have in a surgeon's</p> <p>2 tool kit, so to speak?</p> <p>3 MR. ZONIES: Object to the form.</p> <p>4 A. I do.</p> <p>5 Q. (By Mr. Koopmann) Did you do professional</p> <p>6 education for the TVT-Obturator sling for Ethicon?</p> <p>7 A. I did, from 2004 to 2010, 2011.</p> <p>8 Q. How many TVT-Obturator slings would you</p> <p>9 estimate that you've implanted?</p> <p>10 A. Close to 200.</p> <p>11 Q. And how many TVT-Abbrevos would you</p> <p>12 estimate that you've implanted in your career?</p> <p>13 A. Approximately 100.</p> <p>14 Q. I'm going to ask you a few follow-up</p> <p>15 questions on some of the studies that Mr. Zonies asked</p> <p>16 you about. Start with Exhibit 13, the Zahn article.</p> <p>17 Do you still have that one in front of you?</p> <p>18 A. Yes.</p> <p>19 Q. Now, you mentioned in response to one of</p> <p>20 Mr. Zonies' questions that there was a controversy</p> <p>21 that exists in your field regarding whether the</p> <p>22 TVT-Obturator -- strike that.</p> <p>23 You mentioned earlier that there's a</p> <p>24 controversy that exists in your field regarding which</p> <p>25 approach for an obturator sling is better, the</p>
<p style="text-align: right;">Page 87</p> <p>1 combined with another procedure that may have required</p> <p>2 a hospital stay.</p> <p>3 Q. Do you think that both the TVT-O and the</p> <p>4 TVT-Abbrevos are safe and effective products?</p> <p>5 A. I do.</p> <p>6 Q. And is that your opinion -- strike that.</p> <p>7 Which sling, the TVT-Obturator or the</p> <p>8 TVT-Abbrevos, has more published data on it?</p> <p>9 A. The TVT-Obturator.</p> <p>10 Q. When you started using the TVT-Obturator in</p> <p>11 2004, did you find that that was a better option for</p> <p>12 some patients in your practice than the TVT-Retropubic</p> <p>13 sling?</p> <p>14 A. I did.</p> <p>15 Q. But were there also patients for whom you</p> <p>16 thought the TVT-Retropubic sling was a better option?</p> <p>17 A. Correct.</p> <p>18 Q. When you leave behind mesh in a TVT-O</p> <p>19 patient after you remove some of the mesh, are you</p> <p>20 leaving behind mesh that you do not believe to be</p> <p>21 causing the plaintiff any problems?</p> <p>22 MR. ZONIES: Object to the form.</p> <p>23 A. That's correct. I remove only what I feel</p> <p>24 is necessary.</p> <p>25 Q. (By Mr. Koopmann) Do you think the</p>	<p style="text-align: right;">Page 89</p> <p>1 inside-out approach or the outside-in approach; is</p> <p>2 that correct?</p> <p>3 MR. ZONIES: Object to the form.</p> <p>4 A. That is correct.</p> <p>5 Q. (By Mr. Koopmann) And this Zahn study is</p> <p>6 one study on one side of that controversy; is that</p> <p>7 fair to say?</p> <p>8 MR. ZONIES: Object to the form.</p> <p>9 A. Correct.</p> <p>10 Q. (By Mr. Koopmann) And it's an anatomic</p> <p>11 study; is that right?</p> <p>12 A. Yes, it's an anatomic study.</p> <p>13 Q. And it says at the top on the first page,</p> <p>14 "Level of Evidence: II"; do you see that?</p> <p>15 A. I do.</p> <p>16 Q. What does that mean?</p> <p>17 A. There's levels of evidence in that pyramid</p> <p>18 as we mentioned, so Level II evidence is just one of</p> <p>19 them. So this is not the highest level of evidence by</p> <p>20 any means.</p> <p>21 Q. Level I evidence is the highest level of</p> <p>22 evidence?</p> <p>23 A. Correct.</p> <p>24 Q. And then I want to direct your attention to</p> <p>25 page 705 of that Zahn study.</p>

<p style="text-align: right;">Page 90</p> <p>1 A. I'd like to go back if I can. I don't</p> <p>2 think this is even Level II evidence. I think that's</p> <p>3 maybe what Dr. Zahn felt it was, but I don't think</p> <p>4 that's even supported.</p> <p>5 MR. ZONIES: Objection; move to strike.</p> <p>6 Q. (By Mr. Koopmann) Bottom left of page 705,</p> <p>7 do you see a paragraph that starts, "Although there</p> <p>8 are anatomic"?</p> <p>9 A. Yes.</p> <p>10 Q. And that paragraph says, "Although there</p> <p>11 are anatomic differences between the two approaches</p> <p>12 for transobturator tape placement relative to</p> <p>13 proximity to neurovascular structures, clinical</p> <p>14 consequences thus far do not seem to significantly</p> <p>15 correlate with theoretical risk based on anatomic</p> <p>16 dissections"; did I read that correctly?</p> <p>17 A. You did, yes.</p> <p>18 MR. ZONIES: Object to form.</p> <p>19 Q. (By Mr. Koopmann) And do you agree with</p> <p>20 that statement?</p> <p>21 A. I do. And that's based on my own clinical</p> <p>22 experience as well as a review of the literature and</p> <p>23 systematic reviews, RCTs. There's not a single</p> <p>24 systematic review that would support one being</p> <p>25 superior over the other in terms of the outcome.</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. (By Mr. Koopmann) And in Exhibit 16, the</p> <p>2 article that you co-authored, turn to page 29, please.</p> <p>3 I direct your attention to the middle column. In the</p> <p>4 middle of that first paragraph, you noted, "We prefer</p> <p>5 an inside-out approach, as this ensures that we will</p> <p>6 have accurate sling placement at the mid-urethra as in</p> <p>7 all of our MUS procedures. Also, the inside-out</p> <p>8 approach has a decreased incidence of bladder injury</p> <p>9 as the trocar is passed away from the bladder, not</p> <p>10 toward it"; did I read that correctly?</p> <p>11 A. You did.</p> <p>12 Q. And in that paragraph, you are saying that</p> <p>13 you prefer the inside-out approach for transobturator</p> <p>14 sling placement over the outside-in approach for those</p> <p>15 reasons; is that fair to say?</p> <p>16 MR. ZONIES: Object to the form.</p> <p>17 A. Yes, that's one main reason.</p> <p>18 Q. (By Mr. Koopmann) And why is it that an</p> <p>19 inside-out approach has a decreased incidence of</p> <p>20 bladder injury because the trocar's passed away from</p> <p>21 the bladder?</p> <p>22 MR. ZONIES: Object to the form.</p> <p>23 Q. (By Mr. Koopmann) Can you explain that to</p> <p>24 me?</p> <p>25 A. Yeah, there's two types of transobturator</p>
<p style="text-align: right;">Page 91</p> <p>1 Q. And the Achtari study that was marked as</p> <p>2 Exhibit Number 14, that's another anatomical study; is</p> <p>3 that correct?</p> <p>4 A. That's correct.</p> <p>5 Q. So not Level I evidence?</p> <p>6 A. Correct. That's not Level I evidence.</p> <p>7 It's even less cadavers that were used in the previous</p> <p>8 study, in the Zahn study.</p> <p>9 Q. And in the Spinosa article that Mr. Zonies</p> <p>10 marked as Exhibit 15, that's another anatomical study;</p> <p>11 is that right?</p> <p>12 A. Yes, of seven cadavers.</p> <p>13 Q. And this is not Level I evidence either, is</p> <p>14 it?</p> <p>15 A. It's not Level I evidence.</p> <p>16 Q. The authors in the Spinosa article noted on</p> <p>17 page 1101 that "It is possible that in the present</p> <p>18 cadaver study the thigh flexion during tape insertion</p> <p>19 was suboptimal because of the rigidity of the</p> <p>20 specimens"; is that right?</p> <p>21 A. That is correct.</p> <p>22 Q. And that was a limitation of -- a possible</p> <p>23 limitation of that anatomic study?</p> <p>24 MR. ZONIES: Object to the form.</p> <p>25 A. Yes, that's a limitation of this study.</p>	<p style="text-align: right;">Page 93</p> <p>1 approaches. There's the outside-to-in, meaning the</p> <p>2 puncture's on the skin, and then the trocar exits in</p> <p>3 the vagina. Then there's the inside-to-out. I prefer</p> <p>4 the inside-to-out approach because you can more</p> <p>5 accurately identify the urethra and the bladder and</p> <p>6 start at the midurethral complex.</p> <p>7 The statement that I've made many times to</p> <p>8 the residents and fellows and students I train is, if</p> <p>9 you start at the midurethra, you end at the</p> <p>10 midurethra. So I prefer all of my midurethral slings</p> <p>11 to start there, whether it's a mini-sling, retropubic</p> <p>12 sling or transobturator sling. And the dissection is</p> <p>13 very straightforward to the obturator foramen. You're</p> <p>14 able to physically dissect the bladder off of the</p> <p>15 ischiopubic rami and then insert your trocar and</p> <p>16 safely pass it away from the bladder towards the legs,</p> <p>17 so there's very little risk of injuring the bladder if</p> <p>18 the procedure's done properly, where, with the</p> <p>19 outside-to-in approach, there's a lot more tunnelling</p> <p>20 that occurs blindly. And so when the tunnelling is</p> <p>21 occurring across the transobturator, you'll more</p> <p>22 likely injure the bladder or the urethra or end up in</p> <p>23 the wrong location, not at the midurethral complex.</p> <p>24 Q. I think you mentioned earlier that you</p> <p>25 relied primarily, or relied heavily on Level I</p>

<p style="text-align: right;">Page 94</p> <p>1 evidence, like prospective randomized control trials, 2 systematic reviews and meta-analyses; is that fair to 3 say? 4 MR. ZONIES: Object to the form. 5 A. Yes. 6 Q. (By Mr. Koopmann) And why is it that you 7 relied primarily on those materials in forming your 8 opinions about the TVT-Obturator sling? 9 MR. ZONIES: Same objection. 10 A. Because they're peer reviewed. They're a 11 summary of the best evidence that's out there. They 12 tend to eliminate bias and opinion. And so that's why 13 we rely on that for all the medical conditions that we 14 treat. If those levels of evidence don't exist, then 15 you do need to rely on lower levels of evidence if 16 it's a product that has not been well-studied. But 17 the TVT product and the TVT-Obturator product are some 18 of the most widely studied medical devices ever, and 19 so why not rely on the most highest levels of evidence 20 when formulating your opinions. 21 Q. And did you review and rely on a Cochrane 22 review by first author named Ford that was published 23 in 2015 regarding midurethral sling operations for 24 stress urinary incontinence in women? 25 A. I did.</p>	<p style="text-align: right;">Page 96</p> <p>1 noted in the middle of the "Main results" section on 2 page 2 with respect to vaginal tape erosion or 3 exposure or extrusion that the rate -- the overall 4 rate was low in both groups, meaning both in the 5 retropubic and the transobturator groups; is that 6 correct? 7 A. It says, "The overall rate of vaginal tape 8 erosion/exposure/extrusion was low in both groups, 24 9 out of 1,000 instances." 10 Q. With transobturator slings? 11 A. With transobturator, 21 out of 1,000 for 12 retropubic. 13 Q. So that's a 2.4 percent rate of vaginal 14 tape erosion, exposure or extrusion with 15 transobturator slings? 16 A. Correct. 17 Q. And further down in the section labeled 18 "Authors' Conclusions," the authors concluded that 19 "Mid-urethral sling operations have been the most 20 extensively researched surgical treatment for stress 21 urinary incontinence in women and have a good safety 22 profile"; is that correct? 23 A. That's correct. 24 MR. ZONIES: Object to the form. 25 Q. (By Mr. Koopmann) They went on to say,</p>
<p style="text-align: right;">Page 95</p> <p>1 Q. Do you have that article in your binder 2 here? I'll ask you a couple of questions about that. 3 MR. ZONIES: I think it's 27, I think. 4 Wait, wait, did I guess right? She needs to hear that 5 I guessed that right, because I'm not as old as she 6 thinks I am now. 7 A. Let me just double-check my references 8 here. Suspense is killing everyone. 9 MR. ZONIES: It's wrong. It's 73. 10 A. So I have 25 is Oga, 27 -- 11 Q. (By Mr. Koopmann) Here, let me make this 12 easier. Let me just give you a copy. 13 A. Okay. Thank you. 14 Q. And it's -- this is a 280-some page 15 document in its entirety, so I have copied some 16 excerpts from it that I want to ask you some questions 17 about. 18 MR. ZONIES: Objection to the editing of 19 the document. 20 Q. (By Mr. Koopmann) If you'll turn to page 21 2, please, of the copy I handed you. 22 MR. KOOPMANN: And we'll mark that as 23 Exhibit 17. 24 (Exhibit 17 was marked for identification.) 25 Q. Page 2 of the Ford/Cochrane review, they</p>	<p style="text-align: right;">Page 97</p> <p>1 "Irrespective of the routes traversed, they are highly 2 effective in the short and medium-term, and accruing 3 evidence demonstrates their effectiveness in the 4 long-term"; did I read that correctly? 5 MR. ZONIES: Object to the form. 6 A. You did. 7 Q. (By Mr. Koopmann) And then they go on to 8 say, "This review illustrates their positive impact on 9 improving the quality of life of women with SUI"; is 10 that right? 11 MR. ZONIES: Object to the form. 12 A. That's correct. 13 Q. (By Mr. Koopmann) If you'll turn to page 14 28 of Exhibit 17, there's a section there dealing with 15 pain. And it notes in the right-hand column there 16 that "Both groin and suprapubic pain occurrence were 17 short-lasting with most resolving within the first six 18 months"; is that correct? 19 MR. ZONIES: Object to the form. 20 A. That's correct. 21 Q. (By Mr. Koopmann) And they're referring to 22 both transobturator and retropubic slings in that; is 23 that correct? 24 MR. ZONIES: Object to the form. 25 A. That's correct.</p>

<p style="text-align: right;">Page 98</p> <p>1 Q. (By Mr. Koopmann) If you'll turn to page 2 30 of the Ford/Cochrane review, you'll see a section 3 discussing sexual function and quality of life 4 measures; do you see that? 5 A. I do. 6 Q. And they say at the bottom of that left 7 column, "In all the trials there was significant 8 improvement in sexual function from baseline scores 9 during the follow-up period that spanned 6 to 24 10 months"; is that right? 11 MR. ZONIES: Object to the form. 12 A. That's correct. 13 Q. (By Mr. Koopmann) They then note, "There 14 were no significant differences between the two 15 groups," meaning the retropubic and transobturator 16 group; is that right? 17 MR. ZONIES: Same objection. 18 A. Correct. 19 Q. (By Mr. Koopmann) And then they noted, "At 20 24-month follow-up, rates of superficial and deep 21 dyspareunia were low, with no difference between the 22 groups"; is that correct? 23 MR. ZONIES: Object to form. 24 A. That is correct. 25 Q. (By Mr. Koopmann) And are these findings</p>	<p style="text-align: right;">Page 100</p> <p>1 MR. ZONIES: Same objection. 2 A. That's correct. 3 Q. (By Mr. Koopmann) And what did these 4 authors find the nine-year cumulative risk of sling 5 revision or removal was in that patient population? 6 A. At one year, the risk was 2.2 percent. 7 This increased to 3.2 percent at four years before 8 plateauing. 9 Q. And they found that the nine-year 10 cumulative risk of sling revision or removal was 3.7 11 percent; is that right? 12 MR. ZONIES: Object to the form. 13 A. That's correct. 14 Q. (By Mr. Koopmann) And they found the 15 nine-year risk of mesh erosion was 2.5 percent; is 16 that correct? 17 MR. ZONIES: Same objection. 18 A. Yes, that's correct. 19 Q. (By Mr. Koopmann) And this is a study that 20 you reviewed and relied on in forming your opinions 21 regarding the TVT-Obturator sling? 22 A. It is. 23 Q. Did you review a systematic review and 24 meta-analysis by Dr. Tommaselli that was published in 25 2015?</p>
<p style="text-align: right;">Page 99</p> <p>1 that we discussed in the Ford/Cochrane review 2 consistent in your experience in treating your 3 patients with transobturator slings? 4 MR. ZONIES: Same objection. 5 A. They're consistent with my review of the 6 medical literature and my own personal experience with 7 the midurethral sling devices. 8 Q. (By Mr. Koopmann) Did you review and rely 9 on an article by lead author Michele Jonsson Funk in 10 formulating your opinions regarding the TVT-O sling? 11 A. I did. 12 Q. I hand you a copy of that. 13 MR. KOOPMANN: If we could mark that as 14 Deposition Exhibit 18. 15 (Exhibit 18 was marked for identification.) 16 Q. This study was a population-based cohort of 17 commercially insured individuals that were treated 18 between 2001 and 2010 with a midurethral sling 19 procedure and any subsequent sling revision/removal; 20 is that right? 21 MR. ZONIES: Object to form. 22 A. Yes, that's correct. 23 Q. (By Mr. Koopmann) And they looked at 24 180,454 women who underwent an index sling procedure; 25 is that right?</p>	<p style="text-align: right;">Page 101</p> <p>1 A. I did. 2 Q. I hand you a copy of that. 3 MR. KOOPMANN: We can mark that as 4 Exhibit 19, please. 5 (Exhibit 19 was marked for identification.) 6 Q. So this is one of the systematic reviews 7 and meta-analyses that you referenced earlier as one 8 of the types of studies that you primarily relied on; 9 is that true? 10 MR. ZONIES: Object to the form. 11 A. Yes, this is one of the systematic reviews 12 that I relied on. 13 Q. (By Mr. Koopmann) And the authors noted in 14 the abstract that the objective of this review was to 15 evaluate the long-term outcomes of retropubic 16 midurethral sling procedures and the medium-term 17 outcomes of transobturator procedures; is that right? 18 MR. ZONIES: Object to the form. 19 A. Yes, that's correct. 20 Q. (By Mr. Koopmann) And if you'll turn to 21 page -- it's the page with Table 3 at the bottom 22 right-hand corner. 23 A. Okay. 24 Q. Table 3, they report the number of patients 25 treated and evaluated in the medium-term and long-term</p>

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<p>1 per type of device; is that right?</p> <p>2 A. That's correct.</p> <p>3 MR. ZONIES: Object to the form. Sorry.</p> <p>4 Q. (By Mr. Koopmann) And the total number of</p> <p>5 transobturator slings studied in this procedure -- or</p> <p>6 this study were 2,432; is that right?</p> <p>7 MR. ZONIES: Same objection.</p> <p>8 A. Looking at all studies, 2,432.</p> <p>9 Q. (By Mr. Koopmann) And that would include</p> <p>10 TVT-O, but it would also include other slings; is that</p> <p>11 right?</p> <p>12 A. TVT-O, Monarc, Aris, TOT, I-Stop TOT, IVS,</p> <p>13 Obtape.</p> <p>14 Q. And then on the next page, you'll see a</p> <p>15 section labeled "Tape-related long-term</p> <p>16 complications"; do you see that?</p> <p>17 A. I do.</p> <p>18 Q. And there they report, "Persistent or</p> <p>19 chronic pain (i.e. pain persisting beyond the</p> <p>20 perioperative period or reported at the last follow-up</p> <p>21 visit) was reported by 13 patients for retropubic</p> <p>22 midurethral slings and 30 patients for transobturator</p> <p>23 midurethral slings"; is that right?</p> <p>24 A. That's correct.</p> <p>25 MR. ZONIES: Object to the form.</p>	<p>1 and efficacy of the TVT-Obturator sling?</p> <p>2 A. Yes.</p> <p>3 Q. This study looked at 3,307 women who</p> <p>4 underwent sling placement; is that right?</p> <p>5 MR. ZONIES: Object to the form.</p> <p>6 A. That's correct.</p> <p>7 Q. (By Mr. Koopmann) And they found that 89</p> <p>8 of those 3,307 women, or 2.7 percent, underwent the</p> <p>9 sling revision for one or more of various indications;</p> <p>10 is that fair to say?</p> <p>11 MR. ZONIES: Same objections.</p> <p>12 A. That's fair to say.</p> <p>13 Q. (By Mr. Koopmann) And in the "Conclusions"</p> <p>14 section of their abstract, they noted that the rate of</p> <p>15 sling revision after midurethral sling placement was</p> <p>16 2.7 percent; is that right?</p> <p>17 MR. ZONIES: Same objections.</p> <p>18 A. Yes, that's right.</p> <p>19 Q. (By Mr. Koopmann) If you'll turn to the</p> <p>20 page that has the "Results" section on the left-hand</p> <p>21 column.</p> <p>22 A. Yes.</p> <p>23 Q. The start of the "Results" section, do you</p> <p>24 see that?</p> <p>25 A. I do.</p>
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<p>1 Q. (By Mr. Koopmann) So while the authors</p> <p>2 don't report this particular calculation, if you do</p> <p>3 that calculation of 30 patients with persistent or</p> <p>4 chronic pain divided by the total number of</p> <p>5 transobturator slings, the rate is 1.2 percent of</p> <p>6 persistent or chronic pain with transobturator slings;</p> <p>7 is that right?</p> <p>8 MR. ZONIES: Object to the form, and the</p> <p>9 math.</p> <p>10 A. Yes, that's correct.</p> <p>11 MR. KOOPMANN: What's wrong with my math?</p> <p>12 MR. ZONIES: None, I'm just -- I'm</p> <p>13 objecting to my inability to confirm your math, and</p> <p>14 that he'll do math for you but not for me.</p> <p>15 Q. (By Mr. Koopmann) Did you also look at a</p> <p>16 study by -- or review a study by Dr. Unger and</p> <p>17 colleagues on the indication and risk factors for</p> <p>18 midurethral sling revision?</p> <p>19 A. I did.</p> <p>20 Q. I have got a copy for you there.</p> <p>21 MR. KOOPMANN: If we could mark that,</p> <p>22 please, as Exhibit 20.</p> <p>23 (Exhibit 20 was marked for identification.)</p> <p>24 Q. Is this a study that you reviewed and</p> <p>25 relied on in forming your opinions about the safety</p>	<p>1 Q. So they note there that of the 3,307 women</p> <p>2 who underwent midurethral sling placement during the</p> <p>3 study period, 89 underwent subsequent sling revision</p> <p>4 for one or more of the following indications: urinary</p> <p>5 retention, 43.8 percent; voiding symptoms, 42.7</p> <p>6 percent; recurrent UTI, 20.2 percent; mesh erosion,</p> <p>7 21.3 percent; vaginal pain/dyspareunia, 7.9 percent;</p> <p>8 and groin pain, 3.4 percent; is that right?</p> <p>9 MR. ZONIES: Object to the form.</p> <p>10 A. That's correct.</p> <p>11 Q. (By Mr. Koopmann) And so for erosions,</p> <p>12 21.3 percent of 89 people had re-operations for</p> <p>13 erosion?</p> <p>14 MR. ZONIES: Same objection.</p> <p>15 A. For erosion, it was 21 percent of the 89,</p> <p>16 so that would be --</p> <p>17 Q. (By Mr. Koopmann) 19 people?</p> <p>18 A. -- approximately 19 people, or 20 people.</p> <p>19 Q. And if you divide 19 people divided by the</p> <p>20 3,307 women, that would yield a re-operation for</p> <p>21 erosion rate of 0.57 percent, per my math. Do you</p> <p>22 think that is correct?</p> <p>23 MR. ZONIES: Object to the form.</p> <p>24 A. Yeah, that's correct.</p> <p>25 Q. (By Mr. Koopmann) And for vaginal pain and</p>

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<p style="text-align: right;">Page 106</p> <p>1 dyspareunia, 7.9 percent of 89 people had a 2 re-operation for vaginal pain or dyspareunia. That 3 would be seven people, is that right, if my math is 4 right? 5 MR. ZONIES: Same objections. It's 6 improper use of scientific articles, improper cross -- 7 or redirect. 8 A. Yes, that would be correct. 9 Q. (By Mr. Koopmann) And -- 10 MR. ZONIES: Leading. 11 Q. (By Mr. Koopmann) -- if you do that math, 12 7 divided by 3,307 would be 0.21 percent for the rate 13 of re-operation for vaginal pain or dyspareunia; is 14 that right? 15 MR. ZONIES: Object to the form. 16 A. Yes, that's correct. 17 MR. ZONIES: Math. 18 Q. (By Mr. Koopmann) Are all of the opinions 19 that you've set forth in your TVT-Obturator report set 20 forth to a reasonable degree of medical and scientific 21 certainty? 22 A. Yes, they are. 23 MR. KOOPMANN: I don't have any other 24 questions for you, Dr. Flynn. Thank you. 25 MR. ZONIES: Doctor, thank you for your</p>	<p style="text-align: right;">Page 108</p> <p>1 I, BRIAN FLYNN, M.D., do hereby certify that 2 I have read the foregoing transcript and that the same 3 and accompanying amendment sheets, if any, constitute 4 a true and complete record of my testimony. 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">_____ Signature of Deponent</p> <p style="text-align: center;">() No Amendments () Amendments Attached</p> <p style="text-align: center;">Subscribed and sworn to before me this _____ day of _____, 2016.</p> <p>Notary Public: _____ Address: _____ _____ My commission expires: _____ Seal:</p> <p style="text-align: center;">MLG</p>
<p style="text-align: right;">Page 107</p> <p>1 time. I would have more but I've run out of time. 2 Thank you. 3 THE WITNESS: Thank you. 4 (Whereupon, the deposition was concluded at 5 11:12 a.m. on April 14, 2016.) 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 109</p> <p>1 REPORTER'S CERTIFICATE 2 STATE OF COLORADO)) ss. 3 COUNTY OF DENVER) 4 5 I, MELANIE L. GIAMARCO, do hereby certify that I am 6 a Registered Professional Reporter and Notary Public within 7 the State of Colorado; that previous to the commencement of 8 the examination, the deponent was duly sworn by me. 9 I further certify that this deposition was taken in 10 machine shorthand by me at the time and place herein set 11 forth, that it was thereafter reduced to typewritten form, and 12 that the foregoing constitutes a true and correct transcript 13 of the proceedings had. 14 I further certify that I am not employed by, related 15 to, nor of counsel for any of the parties herein, nor 16 otherwise interested in the result of the within litigation. 17 In witness whereof, I have affixed my signature and 18 seal this 15th day of April, 2016. 19 20 21 22 23 24 25</p> <p style="text-align: center;">Melanie L. Giamarco Registered Professional Reporter Registered Merit Reporter Certified Realtime Reporter My commission expires: August 25, 2017.</p>

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